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Title: Margaret M. Heckler, Secretary of Health and Human Services, Petitioner
v.
Larry Leon Chaney, et al.

Court: United States Court of Appeals for the District of Columbia Circuit

Counsel for petitioner: Solicitor General

Counsel for respondent: Kendall, David E.

Entry	Date	Note	Proceedings and Orders
1	Apr 6 1984		Application for extension of time to file petition and order granting same until May 16, 1984 (Chief Justice, April 12, 1984).
2	May 16 1984	G	Petition for writ of certiorari filed.
3	Apr 11 1984		Response to above application filed.
4	Mar 20 1984		Application for stay filed.
5	Mar 21 1984		Response requested - Due Mar. 23, 1984.
6	Mar 21 1984		Application for stay temporarily granted by The Chief Justice.
7	Mar 26 1984		Response filed.
8	Mar 30 1984		Application for stay GRANTED by The Chief Justice
9	May 29 1984		DISTRIBUTED. June 14, 1984
10	May 25 1984	X	Brief of respondents Larry Leon Chaney, et al. in opposition filed.
11	May 25 1984	G	Motion of respondents for leave to proceed in forma pauperis filed.
12	Jun 8 1984	X	Reply brief of petitioner Heckler, Sec. of HHS filed.
13	Jun 18 1984		Motion of respondents for leave to proceed in forma pauperis GRANTED.
14	Jun 18 1984		Petition GRANTED.
			**********
15	Jun 25 1984		Record filed.
16	Jun 25 1984		Certified original record on appeal & C.A. proceedings received.
17	Jul 6 1984		Order extending time to file brief of petitioner on the merits until August 15, 1984.
20	Jul 6 1984		Order extending time to file brief of respondent on the merits until September 29, 1984.
21	Aug 16 1984		Brief amicus curiae of Washington Legal Foundation filed.
22	Aug 16 1984		Joint appendix filed.
23	Aug 16 1984		Brief of petitioner Heckler, Sec. of HHS filed.
24	Sep 28 1984		Brief amicus curiae of Public Citizen filed.
25	Sep 29 1984		Brief amicus curiae of American Society of Law and Medicine, et al. filed.
26	Sep 29 1984		Brief of respondents Larry Leon Chaney, et al. filed.
27	Oct 19 1984		CIRCULATED.
28	Oct 22 1984		SET FOR ARGUMENT. Monday, December 3, 1984. (2nd case)
29	Nov 23 1984	X	Reply brief of petitioner Heckler, Sec. of HHS filed.
30	Dec 3 1984		ARGUED.

PETITION FOR WRIT OF CERTIORARI

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No.

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In the Supreme Court of the United States

OCTOBER TERM, 1983

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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102 pp

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QUESTIONS PRESENTED

1. Whether the Administrative Procedure Act, 5 U.S.C. 701-706, authorizes judicial review of the Food and Drug Administration's decision not to regulate the states' use, in carrying out capital punishment by lethal injection, of drugs that have been approved for other purposes but that have not been found to be "safe and effective" as a means of causing death.

2. If the FDA's decision not to regulate the states' use of drugs in carrying out capital punishment by lethal injection is subject to judicial review, whether that decision was properly overturned.

PARTIES TO THE PROCEEDING

Margaret M. Heckler, Secretary of Health and Human Services, is the only petitioner. In addition to Larry Leon Chaney, the respondents are Alton Franks, Carl Morgan, Charles W. Davis, Robyn Parks, Doyle Skillern, Jerry Joe Bird, and Henry Martinez Porter.

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In the Supreme Court of the United States

OCTOBER TERM, 1983

No.

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The Solicitor General, on behalf of the Secretary of Health and Human Services, petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-58a) is reported at 718 F.2d 1174. The opinion on denial of rehearing (App., *infra*, 59a-62a) is reported at 724 F.2d 1030. The opinion of the district court (App., *infra*, 63a-79a) and the decision of the Food and Drug Administration (App., *infra*, 81a-86a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on October 14, 1983. A timely petition for rehearing was

denied on January 17, 1984. By order of April 12, 1984, the Chief Justice extended the time within which to file a petition for a writ of certiorari until May 16, 1984. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(a).

STATUTES INVOLVED

Relevant provisions of the Administrative Procedure Act, 5 U.S.C. 551 *et seq.*, and the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, are reprinted at App., *infra*, 95a-96a.

STATEMENT

In recent years, numerous states have enacted statutes prescribing lethal injection as the method for carrying out the death penalty.[1] In this case, prison inmates sentenced to death by lethal injection in Texas and Oklahoma petitioned the Food and Drug Administration (FDA) to block their executions on the ground that the states proposed to employ drugs that had been approved by the FDA as safe and effective for medical purposes but not for human execution. Respondents asserted that their execution by this means would violate the "misbranding" provisions of the Food, Drug, and

[1] These statutes include: Ark. Stat. Ann. § 41-1352 (Supp. 1983); Idaho Code § 19-2716 (Supp. 1983); Ill. Rev. Stat. ch. 38, § 119-5 (Supp. 1984); Mont. Code Ann. § 46-19-103(3) (1983) (prisoner given choice of hanging or lethal injection); Nev. Rev. Stat. § 176.355 (1979); 1983 N.J. Laws 245; N.M. Stat. Ann. § 31-14-11 (Supp. 1983); N.C. Gen. Stat. § 15-187 (1983) (choice of lethal gas or lethal injection); Okla. Stat. Ann. tit. 22, § 1014 (Supp. 1983); Tex. Crim. Proc. Code Ann. § 43.14 (Vernor Supp. 1984); Utah Code Ann. § 77-18-5.5 (1983) (choice of firing squad or lethal injection); Wash. Rev. Code § 10.95.180 (Supp. 1984) (choice of hanging or lethal injection).

Cosmetic Act (FDCA), 21 U.S.C. 331(k), 352. They requested the FDA, among other things, to "[a]dopt a policy and procedure for the seizure and condemnation from prisons or state departments of corrections of drugs which are destined or held for use as a means of execution" and to recommend the criminal prosecution of prison officials and others who "knowingly buy, possess, [sell] or use drugs for the unapproved use of lethal injections" (App., *infra*, 6a).

The FDA declined to take the requested enforcement actions. It concluded (App., *infra*, 81a-86a) that it lacked jurisdiction under the FDCA and that, in any event, it would decline to act as a matter of its enforcement discretion. The Commissioner of Food and Drugs stated (*id.* at 82a, 85a):

> Our conclusion that the use of lethal injection is not subject to our jurisdiction is supported by the relevant statutory provisions, by our current policy on the use of approved drugs for unapproved uses, and by a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems.
>
> * * * * *
>
> The unapproved use of approved drugs is an area in which the case law is far from uniform. Generally, enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper state functions.
>
> Were FDA clearly to have jurisdiction in this area, moreover, we believe we would be authorized to decline to exercise it under our inherent discre-

tion to decline to pursue certain enforcement matters.

Plaintiffs then brought this suit for injunctive and declaratory relief in the United States District Court for the District of Columbia. The district court dismissed the complaint on the ground that the enforcement decisions of an agency are not subject to judicial review. App., *infra*, 63a-79a.

A divided panel of the court of appeals vacated the district court's judgment and remanded with directions "to order the agency to fulfill its statutory function" (App., *infra*, 36a). The court of appeals concluded that the FDA has authority under 21 U.S.C. 331(k) to regulate the use of drugs in administering capital punishment. That provision prohibits the "misbranding" of drugs while they are "held for sale." The court apparently reasoned (App., *infra*, 14a-15a) that the states' use of the drugs for an unapproved purpose constitutes "misbranding" and that the drugs are "held for sale" when they are injected into the person condemned to death.

The court of appeals also held that the FDA's decision not to initiate enforcement activity was subject to judicial review (App., *infra*, 17a-30a). In the court's view (*id.* at 18a-22a), all agency action, including a decision not to begin enforcement proceedings, is presumptively reviewable except in those situations "where the governing statute is 'drawn in such broad terms that in a given case there is no law to apply.'" The court observed (*id.* at 24a) that the "determination of whether there 'is law to apply' turns on such pragmatic considerations as whether judicial supervision is necessary to safeguard plaintiff's interests, whether judicial review

will unnecessarily impede the agency in effectively carrying out its congressionally assigned role, and whether the issues are appropriate for judicial review.'" In this case, the court found "law to apply" in the preface to an FDA rule proposed for notice and comment in 1972 but never promulgated.[2] The court concluded (*id.* at 31a-35a) that the FDA's reasons for declining enforcement were irrational in light of the preface and warned (*id.* at 37a): "We must be prepared to compel FDA to take action with respect to the [plaintiffs'] prayer for relief where an acceptable explanation of [FDA's] inaction is not promptly forthcoming."[3]

Judge Scalia dissented (App., *infra*, 39a-58a), stating (*id.* at 39a) that the majority's decision constituted "a clear intrusion upon powers that belong to Congress, the Executive Branch, and the states." He pointed out (*id.* at 46a) that "far from there being a 'presumption of reviewability' with regard to enforcement determinations, the well known presumption is precisely the contrary." Finding no special circumstances justifying review in this case, Judge Scalia concluded that review

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[2] The preface stated (App., *infra*, 24a):

> Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the [FDA] is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public * * *. When necessary the [FDA] will not hesitate to take whatever action is warranted to protect the public.

[3] Although the court of appeals acknowledged that "the state may take the life of a person as punishment" and that the "FDA is not responsible for the execution of these prisoners," the court observed that the "FDA's impermissible refusal to exercise enforcement discretion over the use of drugs for lethal injection * * * may also implicate the Eighth Amendment's prohibition of cruel and unusual punishment." App., *infra*, 37a, 38a.

was unavailable. He noted (*id.* at 49a-51a) that the preamble on which the majority relied had never been adopted. He also observed (*id.* at 48a-49a) that even if the preamble had some effect, it was "full of flexible terms, the precise application of which was obviously intended to be, and could properly be, left to the discretion of the agency—for example whether an unapproved use has become 'widespread.'"

Moreover, assuming that the FDA's decision not to undertake enforcement action was judicially reviewable, Judge Scalia found (App., *infra*, 51a-58a) that the FDA's actions were not arbitrary and capricious. He concluded that the FDA had no statutory authority to take the requested action because "[u]nder no conceivable interpretation of the English language could [the drugs used in legal injections] be deemed 'held for sale'" (*id.* at 55a).

By a five-to-five vote, the court of appeals denied the government's suggestion for rehearing en banc (App., *infra*, 59a-60a).[4] In a statement joined by Judges Wilkey, Bork, and Starr, Judge Scalia stressed (*id.* at 60a) the significance of the holding of this case to "the enforcement authority of all federal agencies."

REASONS FOR GRANTING THE PETITION

The decision of the court of appeals is in direct conflict with decisions of two other circuits. It usurps the traditional enforcement discretion of the executive branch and diverts the Food and Drug Administration

[4] Judges Wilkey, Ginsburg, Bork, Scalia, and Starr voted to grant rehearing en banc. Judges Wright, Tamm, Wald, Mikva, and Robinson voted against rehearing en banc. Judge Edwards abstained.

from the important responsibilities assigned by Congress; it unjustifiably interferes with the states' lawful exercise of their power to enforce their criminal laws; and it makes a mockery of the Food, Drug, and Cosmetic Act. Review by this Court is clearly warranted.

1. The decision below squarely conflicts with decisions of the Fifth and Eighth Circuits. In *O'Bryan* v. *McKaskle*, 729 F.2d 991 (1984) (App., *infra*, 88a-94a), a Texas prisoner sentenced to death by lethal injection brought suit against the state authorities, claiming among other things that execution by lethal injection violated the Food, Drug, and Cosmetic Act as interpreted by the court of appeals in the instant case. Refusing to stay his execution, the Fifth Circuit expressly disagreed with the court of appeals' decision in this case (App., *infra*, 92a-93a):

> On the probable merits of O'Bryan's claim of a violation of the Act, we think that for the reasons set forth in Judge Scalia's dissenting opinion in *Chaney*, O'Bryan's claim is insubstantial and he is unlikely to succeed on appeal.

This Court also refused to enter a stay (*O'Bryan* v. *McKaskle*, Nos. A-786 & A-787 (Mar. 30, 1984)),[5] and O'Bryan was executed.

The court of appeals' holding concerning judicial review of FDA enforcement decisions conflicts with the

[5] In addition, the Court refused O'Bryan's request for an order requiring the FDA to seize the drugs intended for use in his execution (*O'Bryan* v. *Heckler*, No. A-791 (Mar. 30, 1984)). Earlier that day, the United States District Court for the District of Columbia had entered such an order (Civ. No. 84-996), but the court of appeals had vacated it (No. 84-996) in light of the stay entered by the Chief Justice in this case (No. A-761) (Mar. 21, 1984).

Eighth Circuit's decision in *National Milk Producers Federation* v. *Harris*, 653 F.2d 339, 340 (1981). In that case, dairy producers sought to compel the FDA to initiate "investigative, enforcement, or prosecutorial proceedings" against persons alleged to be violating the FDCA by selling misbranded cheese substitutes in interstate commerce. Affirming the dismissal of the dairy producers' complaint, the Eighth Circuit stated (653 F.2d at 343) that "[t]he executive branch and its departments enjoy a discretion in the initiation of * * * enforcement * * * actions limited only by constitutional strictures and relevant statutory directives." The court concluded (*id.* at 344 (footnote omitted)): "After carefully reviewing the [FDCA] we have found no provision which narrows or limits the discretion of the FDA to investigate, enforce, or prosecute alleged violations of the Act or its regulations."

2. a. The court of appeals' decision in this case is also plainly wrong. First, in holding that the FDA's exercise of enforcement discretion was subject to judicial review, the court departed dramatically from settled principles of administrative law.

The Administrative Procedure Act, 5 U.S.C. 701(a)(2), provides that final agency action is not subject to judicial review if it is "committed to agency discretion by law." This bar to judicial review applies where the governing "'statutes are drawn in such broad terms that in a given case there is no law to apply.'" *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 410 (1971) (quoting S. Rep. 752, 79th Cong., 1st Sess. 26 (1945)).

This is a paradigmatic case in which the governing statute provides "no law to apply." The FDCA does not

command the FDA to initiate investigative or enforcement activity whenever a statutory violation is alleged or found.[6] Indeed, the Act does not even suggest the standards to be used by the FDA in determining whether and when to undertake such activity. Instead, the Act confers upon the Commissioner of Food and Drugs a "broad discretion—broad enough undoubtedly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of the law." *United States* v. *Sullivan*, 332 U.S. 689, 694 (1948). See also 21 C.F.R. 10.45(d)(2)(i) (initiation of FDA enforcement proceedings discretionary). Because most statutes granting enforcement powers to administrative agencies are cast in similar terms, it is well established that agency enforcement decisions are not subject to judicial review, absent special circumstances.[7] See, *e.g.*, *Southern Ry.* v. *Seaboard Al-*

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[6] The court of appeals suggested (App., *infra*, 26a n.29) that Congress intended for the courts to review the FDA's enforcement decisions because the "FDCA's prohibitions are phrased in mandatory terms. *See, e.g.*, 21 U.S.C. 333(a) (any person who violates § 331 'shall' be imprisoned or fined) * * *." However, virtually every law prescribing the penalty for a federal crime is couched in precisely the same language. See, *e.g.*, 18 U.S.C. 371 (anyone convicted of conspiracy "shall" be imprisoned not more than five years or fined not more than $10,000). By the court of appeals' reasoning, Congress must have intended to empower the courts to review federal prosecutors' decisions concerning the bringing of charges under all of these statutes. But see *United States* v. *Nixon*, 418 U.S. 683, 693 (1974).

We note in this regard that nothing in the court of appeals' decision limits the court's holding to administrative—as opposed to criminal—enforcement decisions. Indeed, plaintiffs in this case sought the initiation of criminal proceedings against state correctional officials and others (see App., *infra*, 6a).

[7] *Dunlop* v. *Bachowski*, 421 U.S. 560 (1975), upon which the court of appeals relied extensively (App., *infra*, 18a & n.22,

lied Milling Corp., 442 U.S. 444, 455-456 (1979) (ICC); *Vaca* v. *Sipes*, 386 U.S. 171, 182 (1967) (NLRB); see also *United States* v. *Batchelder*, 442 U.S. 114, 124 (1979) (criminal prosecution); *Bordenkircher* v. *Hayes*, 434 U.S. 357, 364 (1978) (same); *Confiscation Cases*, 74 U.S. (7 Wall.) 454 (1869) (forfeiture proceedings).

In concluding that the FDA's decision here was judicially reviewable, the court of appeals started (App., *infra*, 18a) from a presumption of reviewability that

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21a-23a & nn. 25-26), involved such special circumstances. In that case, a defeated candidate for union office sought to compel the Secretary of Labor to bring suit under provisions of the Labor-Management Reporting and Disclosure Act (LMRDA), 29 U.S.C. 482(a) and (b), to have the election set aside. In holding that the Secretary's refusal to bring suit was reviewable, this Court did not discuss the Secretary's contention that the decision was an unreviewable exercise of prosecutorial discretion, but instead merely expressed agreement (421 U.S. at 567 n.7) with the court of appeals' treatment of the issue. See *Buchowski* v. *Brennan*, 502 F.2d 79 (3d Cir. 1974). The court of appeals noted that the exercise of enforcement discretion is generally unreviewable (see 502 F.2d at 86-87), but distinguished the case on three grounds. First, the court concluded (*id.* at 87), based on the legislative history of the LMRDA, that in empowering the Secretary to bring suit to set aside an election, Congress intended the Secretary to act on behalf of aggrieved union members rather than merely on behalf of the public. Second, it noted (*id.* at 87-88) that union members have no remedy if the Secretary does not act. And third, the court observed (*id.* at 88) that the Secretary's discretion was restricted by statute because he was required to bring suit whenever there was probable cause to believe that there had been a violation affecting the outcome of the election and no settlement was reached.

None of these factors applies here. FDA enforcement is intended to protect the general public, not to redress individual wrongs; persons such as plaintiffs in this case can challenge their sentences in a variety of other ways; and under the FDCA, the FDA has the traditional broad scope of enforcement discretion.

stood this case law on its head. The court then offered the startling suggestion (*id.* at 24a (emphasis added)) that whether there is "law to apply" turns on various "*pragmatic* considerations," such as the need for judicial supervision to safeguard the plaintiffs' interests, the impact of review on the agency's effectiveness, and the appropriateness of the issues raised for judicial review. This formulation converts a straightforward question of statutory interpretation—whether Congress intended the courts to review an agency's enforcement decisions—into an essentially standardless, legislative decision—whether, in the court's judgment, such review would be beneficial. As Judge Scalia noted in his dissent from the denial of rehearing en banc (App., *infra*, 61a), this test means that the court is free to intervene whenever it "think[s] it a good idea."

The court of appeals found no need to "delve into a detailed analysis" of "pragmatic considerations" in the present case because it determined (App., *infra*, 24a) that the FDA had "made law to govern and guide its discretion in regulating the unapproved use of approved drugs." But the "law" upon which the court relied was the preamble to a rule that was proposed for notice and comment[8] but was never adopted by the agency. This unadopted preamble obviously was never intended to be a definitive, judicially enforceable statement of how the agency would exercise its enforcement discretion. As Judge Scalia noted in dissent (App., *infra*, 48a-49a), the preamble was full of flexible terms that are not sus-

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[8] *Legal Status of Approved Labeling for Prescription Drugs: Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed. Reg. 16503 (1972).

ceptible to judicial review. The preamble stated (see *id.* at 24a (emphasis added)), for example, that "[w]here the unapproved use of an approved new drug becomes *widespread* or *endangers the public health*, the Food and Drug Administration is obligated to investigate it thoroughly and to take *whatever action is warranted* to protect the public health." What is "widespread" use? What constitutes a sufficient danger to the public health? And in a given case, what action is "warranted"? It is evident that these questions cannot be answered intelligently without surveying the potential dangers posed by all the foods and drugs marketed in this country and all the resources at the FDA's command. We do not see how the courts could perform that function without taking over day-to-day operation of the agency.

In sum, the FDA's decision not to initiate enforcement action in this case was committed to agency discretion by law and therefore was not judicially reviewable. The court of appeals' contrary conclusion, as Judge Scalia observed, "usurps the authority of the Executive Branch" and "rests upon a novel interpretation of Supreme Court precedent" (App., *infra*, 60a).

b. Even if the FDA's decision were reviewable, it nonetheless should have been upheld. In those special circumstances in which judicial review of administrative enforcement decisions is allowed, the scope of review is limited to determining whether the agency has stated a rational basis for its decision. *Dunlop* v. *Bachowski*, 421 U.S. 560, 568, 572-573 (1975). That standard was easily met here.

First, the FDA was correct in finding that it lacked authority to prevent the states from employing the

drugs at issue in carrying out death sentences. The statutory provision upon which the court of appeals relied, 21 U.S.C. 331(k), prohibits the "misbranding" of drugs while they are "held for sale." This provision simply cannot have been intended by Congress to reach the forcible administration of a lethal injection to a person lawfully condemned to death.[9] See App., *infra*, 54a-58a (Scalia, J., dissenting); cf. *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981). The peculiar nature of the court of appeals' statutory construction is highlighted by the fact that Section 331(k) applies equally to "drug[s]" and "device[s]" and the fact that the statutory definition of a "device" seems clearly to encompass many of the paraphernalia traditionally used for execu-

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[9] In concluding that the FDA possessed the authority to grant respondents' requested relief, the court of appeals repeatedly referred to the FDA's actions regarding drugs used to destroy animals and drugs administered to prisoners participating in research projects. App., *infra*, 11a-12a, 31a, 32a. These situations, however, are clearly distinguishable.

In *United States* v. *Beuthanasia-D Regular*, [1979 Transfer Binder] Food, Drug, Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb.), upon which the court of appeals relied (App., *infra*, 12a), the FDA did not assert authority over the *use* of drugs to destroy animals. That case instead involved the *marketing* of such drugs. Thus, the case was of the type in which FDA normally assumes jurisdiction—the marketing and promoting by a manufacturer of a drug for a purpose that has not been subject to pre-marketing approval. Moreover, the FDA's statutory authority with respect to animal drugs differs from its authority with respect to human drugs. See 21 U.S.C. 360b(a)(1).

The FDA also has special statutory authority to regulate the use of drugs in research projects (see 21 U.S.C. 355(i), 357(d), 360j(g)), participation in which in any event is voluntary. The regulations to which the court of appeals referred (App., *infra*, 12a n.17) implement such special statutory provisions and therefore have no relevance here.

tions, such as the gallows and the electric chair. 21 U.S.C. 321(h).[10] Congress may not have contemplated executions by lethal injection when it enacted the FDCA in 1938, but it certainly was familiar with these "devices." We are aware of no evidence, and the court below cited none, indicating that Congress intended to empower the FDA to regulate the use of such devices.

Second, even if the FDCA could somehow be stretched to reach the administration of lethal injections for purposes of capital punishment, the FDA had sound reasons for declining to intervene. Regulating the method of capital punishment used by the states, whether or not technically within the scope of the FDCA, is far removed from the FDA's central responsibilities. Surely the FDA acted reasonably in conserving its limited enforcement resources for matters more closely related to its principal mission.

The FDA's decision also was based upon a proper consideration for the principles of federalism. The FDA justifiedly expressed reluctance to interfere with the states' administration of lethal injection laws, "which are duly authorized statutory enactments in furtherance of proper State functions" (App., *infra*, 85a). En-

[10] 21 U.S.C. 321(h) defines a "device" to include

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—* * * * *
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

acting laws to prevent and punish crime is among the most important powers of the states, and in prescribing lethal injection as the method of execution, the states acted within federal constitutional limits. The FDA was reasonable in deferring to the states' authority in this field.

Finally, the FDA concluded (App., *infra*, 85a) that state lethal injection laws did not pose a "serious danger to the public health." The court of appeals disagreed (*id.* at 5a), asserting that there was "a substantial threat of torturous pain to persons being executed." However, not only is the factual basis for the court's conclusion dubious (see *id* at 51a-52a & n.5), but the court appears entirely to have missed the point. The proper inquiry is not whether death by lethal injection involves pain but whether it involves more pain than death by alternative methods of execution, such as the electric chair, the firing squad, or the gas chamber. As Judge Scalia put it (*id.* at 51a), "it is not a matter of pain versus no pain, but rather pain of one sort substituted for pain of another—*and in all likelihood substitution of a lesser pain, since that is the principal purpose of the lethal injection statutes.*" Such comparisons were made by the legislatures that enacted the lethal injection statutes. The FDA acted responsibly in declining to review their determinations on this unique subject.

3. a. If not reversed, the court of appeals' decision will have extremely harmful practical consequences. The FDA will be compelled to intervene in a highly controversial area far removed from its proper responsibilities, at the expense of performing its intended mission

of protecting the consuming public from dangerous and misbranded drugs.

Furthermore, the decision below is likely to interfere with state enforcement of capital punishment statutes that satisfy Eighth Amendment standards. As noted, the court of appeals held that the "misbranding" provision of the FDCA (21 U.S.C. 331(k)) prohibits the use, in carrying out capital punishment, of drugs that have been approved for other purposes but not for the purpose of causing death. The court also effectively held that the FDA must take action to prevent this statutory "violation."[11] Consequently, at a minimum, the decision below will prevent executions by lethal injection until a manufacturer or other party seeks FDA approval for use of the drugs in executions and demonstrates to the FDA that they are "safe and effective" in causing death (21 U.S.C. 355(a)). Moreover, it is doubtful whether any manufacturer or other firm will seek such approval in view of the expense involved, the organized opposition to capital punishment, and the very small quantities of drugs that would be sold for this new use. Thus, the practical effect of the court of appeals' decision might well be to prevent executions by lethal injection altogether.

In the long run, the court of appeals' decision may have an ironic effect. States have recently enacted statutes prescribing lethal injection as the method of carrying out death sentences precisely because that is thought to be the least painful method available. If the court of appeals' decision is allowed to stand, it may compel the states to resort to older and potentially more painful methods.

b. The court of appeals' holding concerning judicial review of administrative enforcement decisions threatens judicial interference with one of the executive branch's core responsibilities. The effective functioning of administrative agencies would be seriously impaired if courts could freely second-guess such decisions. In deciding how to employ their limited enforcement resources, agencies generally concentrate on those efforts that are most needed and offer the greatest chances of success. Such choices are necessarily based in large measure on policy considerations and discretion. Thus, judicial review in this area will almost certainly result in the substitution of the preferences of the judicial branch for those of the executive. See App., *infra*, 39a (Scalia, J., dissenting). This alteration of the separation of powers deserves review by this Court.

[11] The court of appeals remanded for the district court to determine whether the FDA's reasons for refusing to initiate enforcement action were sufficient (see App., *infra*, 31a). However, the court of appeals' opinion left no doubt that in its view all of the FDA's proferred justifications were unsound (*id.* at 30a-35a).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MAY 1984

UNITED STATES COURT OF APPEALS, DISTRICT OF COLUMBIA CIRCUIT

No. 82-2321

LARRY LEON CHANEY, ET AL., APPELLANTS,

v.

MARGARET M. HECKLER, AS SECRETARY OF HEALTH AND HUMAN SERVICES.

Argued May 20, 1983
Decided Oct. 14, 1983

Appeal from the United States District Court for the District of Columbia (D.C. Civil Action No. 81-02265).

Before WRIGHT and SCALIA, Circuit Judges, and WEIGEL,* Senior District Judge.

Opinion for the court filed by Circuit Judge J. SKELLY WRIGHT.

Dissenting opinion filed by Circuit Judge SCALIA.

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*Of the United States District Court for the Northern District of California, sitting by designation pursuant to 28 U.S.C. § 294(d) (Supp. V 1981).

J. SKELLY WRIGHT, Circuit Judge:

In the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* (1976 & Supp. V 1981), Congress has required the Secretary of Health and Human Services or her delegate, the Commissioner of the Food and Drug Administration (FDA),[1] to assure that all "new drugs" are "safe and effective" for use under the conditions prescribed, recommended, or suggested on the official labeling.[2] *Id.* ; § 355(a). Before the Commissioner can allow a "new drug" to be distributed in interstate commerce, FDA must assure the safety of the drug and the adequacy of its branding. *Id.* §§ 331, 355; *see also* 21 C.F.R. § 201 *et seq.* (1983). A drug is "misbranded," and impermissibly available for use by consumers, unless its labeling bears adequate directions for use and such adequate warnings against unapproved uses or methods of administration as are necessary for the protection of its users. 21 U.S.C. § 352(f). The Commissioner has previously interpreted FDCA's labeling requirements to impose upon FDA the "obligat[ion]" to

[1] *See* 21 C.F.R. § 5.10 (1983) (delegating authority to the Commissioner of FDA).

[2] The statute defines the term 'new drug" to mean "[a]ny drug * * * not generally recognized, among experts * * *, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *" 21 U.S.C. § 321(p)(1) (1976).

The Supreme Court has interpreted drugs to be "safe and effective" when there is an "expert consensus" founded upon "substantial evidence," as defined at 21 U.S.C. § 355(d). *See United States* v. *Rutherford*, 442 U.S. 544, 549-550 n. 7, 99 S.Ct. 2470, 2473-2474 n. 7, 61 L.Ed.2d 68 (1979).

investigate and take appropriate action against unapproved uses of approved drugs where such unapproved use becomes widespread or endangers the public health. *See Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed.Reg. 16503, 16504 (August 15, 1972) (hereinafter *Policy Statement).*[3]

In this case we review FDA's decision to take *no* action—either investigatory or regulatory—against the unapproved use of approved drugs in state capital punishment systems. Appellants, eight prison inmates under sentence of death in Texas and Oklahoma,[4] claim that FDA has arbitrarily and capriciously refused to prevent the use of drugs not proven "safe and effective" as a means of human execution.[5] Their petition to FDA

[3] FDA may enforce the statute by obtaining court-ordered injunctions, 21 U.S.C. § 332(a), fines and imprisonment, *id.* § 333, and seizures, *id.* § 334(a). FDA may also promulgate regulations and hold hearings, conduct examinations and investigations, require record keeping, make inspections, and issue public reports. *Id.* §§ 371-375.

In the area of unapproved uses of approved drugs, FDA has indicated that it will take, depending upon the facts of each case, any of the following actions: requiring a labeling change, approving the unapproved use, restricting the channel of distribution, and withdrawing the drug from the market. *See Policy Statement*, 37 Fed. Reg. at 16504.

[4] Originally only Larry Leon Chaney and Doyle Skillern were on the petition. The remaining six appellants joined the petition by letter of January 12, 1981.

[5] *See* Letter dated December 19, 1980 from counsel for appellants to Secretary, Department of Health and Human Services (hereinafter Letter to the Secretary) at 18-19, JA 31-32. A United States District Court has previously approved FDA's assertion that drugs used in animal euthanasia must be "safe and effective" and has approved the relevant criteria for making

asserted that use of barbiturates and paralytics as capital punishment devices, without prior FDA approval, violates the "new drug" and "misbranding" provisions of FDCA, *see* 21 U.S.C. §§ 352, 355.[6] FDA, in response, asserted that its jurisdiction did not extend to the regulation of state-sanctioned use of lethal injections and that, even if it did, FDA would, as a matter of its inherent enforcement discretion, undertake no investigatory or regulatory activity. Letter dated July 7, 1981 from the Commissioner to appellants' counsel (hereinafter Letter from the Commissioner), Joint Appendix (JA) 86-89. The District Court granted summary judgment against appellants' challenge to FDA's inaction. *See* Memorandum Opinion filed August 30, 1982 in D.D.C. Civil Action No. 81-2265 (hereinafter Dist.Ct.Op.), JA 215-231. Because we believe that FDA arbitrarily and capriciously refused to exercise its regulatory jurisdiction, we vacate the District Court's judgment and remand the case to it for further action consistent with this opinion.

I. BACKGROUND

During the last six years at least five states, including Texas and Oklahoma, have enacted statutes adopting lethal injection as a means of human execution.[7] Prisons in these five states house over 200 of the

such determinations. *See United States* v. *Beuthanasia-D. Regular*, [1979 Transfer Binder] Food Drug Cosm.L.Rep. (CCH) ¶ 38265, at 39129 (D.Neb. 1979).

[6] Letter to the Secretary, *supra* note 5, at 3, 5, JA 16, 18.

[7] *See, e.g.*, Idaho Code § 19-2716, as amended by Idaho H.B. No. 752, Amendment to Section 1 (2d Sess., 46th Leg.) (March 31, 1982); N.M. Stat. 31-14-11; Okla. Stat. Tit. 22, § 1014; Tex. Crim.Pro. Code § 43.14; Wash.Rev. Code § 10.95.180.

approximately 1,100 persons sentenced to death in the United States, and at least six other states (with 300 persons on death row) apparently are considering adopting lethal injection as a means of capital punishment.[8] On December 7, 1982 Texas became the first state to actually administer a lethal injection to a condemned inmate.[9]

Because the lethal injection statutes authorize state prison officials to make unapproved use of drugs distributed in interstate commerce, appellants petitioned FDA to enforce the Act against the states.[10] Their December 19, 1980 petition recited the known evidence concerning lethal injection, which strongly indicates that such drugs pose a substantial threat of torturous pain to persons being executed. ROYAL COMMISSION ON CAPITAL PUNISHMENT, 1949-1953 REPORT (1953), Exhibit 1 to Letter dated December 19, 1980 from counsel for appellants to the Secretary of Health and Human Services (hereinafter Letter to the Secretary), JA 34-40. Appellants appended to their petition affidavits of leading medical and scientific experts which aver that there is no "expert consensus" founded upon "substantial evidence" that these drugs will produce death quickly and without pain and discomfort. Exhibit 2 to Letter to the Secretary, JA 43-83. Indeed, these affiants were not aware of *any* published data or investigations that would establish the effectiveness of such

[8] Brief for appellants at 3.

[9] Brief for appellee at 3 n.3.

[10] Filing of a citizen's petition is authorized and governed by 21 U.S.C. § 360g(a) & (f) and 21 C.F.R. § 10.30 (1983).

drugs for lethal injection. *Id.* With this evidence as grounds, appellants requested that FDA take the following actions:

> 1. Affix a boxed warning to the labels of the drugs specified for use in a lethal injection by statutes or prison policies in Texas, Oklahoma, Idaho and New Mexico that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution[;]
>
> 2. Prepare and send to the manufacturers of the drugs and to prisons and departments of corrections in Texas, Oklahoma, Idaho and New Mexico * * * notices advising that the drugs specified in those states' execution statutes or prison policies for use in an execution as well as any other drug or drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;
>
> 3. Place in the Drug Bulletin an article advising that the drugs specified for use in a lethal injection by statutes or prison policies in Texas, Oklahoma, Idaho and New Mexico are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;
>
> 4. Adopt a policy and procedure for the seizure and condemnation from prisons or state departments of corrections of drugs which are destined or held for use as a means of execution; [and]
>
> 5. Recommend the prosecution of manufacturers, wholesalers, retailers and pharmacists who knowingly sell drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess or use drugs for the unapproved use of lethal injections.

Letter to the Secretary at 18-19, JA 31-32. In addition, appellants requested an evidentiary hearing on any issue of controlling fact. *Id.* at 19, JA 32.[11]

On July 7, 1981 the Commissioner of FDA, by letter, refused to take any of the actions requested in appellants' petition. Letter from the Commissioner at 2, JA 87. Rather than investigate appellants' claims, the Commissioner asserted that FDA's jurisdiction did not extend to the regulation of state-sanctioned use of lethal injections. *Id.* Indeed, because these were "duly authorized statutory enactments [that furthered] * * * proper State functions," the Commissioner indicated that, even if it had jurisdiction, FDA would not gather any evidence or pursue any enforcement. *Id.* at 3, JA 88. He noted two reasons for refusing to investigate or to enforce: (1) the case law on the unapproved use of drugs otherwise approved by FDA was not uniform, and (2) FDA had a policy of not initiating enforcement action against unapproved uses of approved drugs absent "serious danger to the public health." *Id.* The Commissioner could find no such "danger" where a state had properly enacted a capital punishment law. *Id.*

On September 16, 1981 appellants filed suit in the District Court seeking to compel FDA to fulfill its statutory obligation to investigate and to regulate the unapproved use of approved drugs in human execution systems. After limited discovery, both appellants and FDA filed cross-motions for summary judgment.

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[11] Hearings may be held in the agency's discretion. 21 C.F.R. § 10.30(h)(2) (1983).

On August 30, 1982 the District Court granted summary judgment to FDA. The court declined to decide the jurisdictional issue, but went on to hold that "decisions of executive departments and agencies to *refrain* from instituting investigations and enforcement proceedings are essentially unreviewable by the courts." Dist. Ct. Op. at 10, JA 224 (emphasis in original). Thus FDA's "decision to refrain from interfering with the implementation of state capital punishment statutes constitutes a defensible exercise of [its] considerable investigative and enforcement discretion * * *." *Id.* at 2, JA 216. The District Court noted that the Commissioner had explained FDA's reasons for not acting, *id.* at 13, JA 227, and, though the court could not review these reasons for their rationality,[12] it therefore found that FDA had not completely abdicated its statutory responsibilities, *id.* at 15, JA 229.

Larry Leon Chaney and the other seven prisoners then filed this appeal.

II. FDA's JURISDICTION OVER LETHAL INJECTIONS

The Commissioner of FDA refused to investigate appellants' allegations or to assess and respond to the evidence they presented. Instead, he asserted that FDA did not have jurisdiction to interfere with state governments' use of prescription drugs for the purpose of causing death by injection. We disagree.

In determining whether FDA has jurisdiction over a particular drug or practice, the Supreme Court has counselled us to inquire "not merely * * * into statutory purpose," but also into the "various sorts of supervision [needed] to effectuate the goals of the Act * * *." *Toilet Goods Ass'n, Inc.* v. *Gardner*, 387 U.S. 158, 163-164, 87 S.Ct. 1520, 1524-1525, 18 L.Ed.2d 697 (1967). Jurisdiction is to be analyzed in terms of "consumer protection, not dialectics." *United States* v. *Urbuteit*, 335 U.S. 355, 357-358, 69 S.Ct. 112, 113-114, 93 L.Ed. 61 (1948). Congress clearly intended that the Act's "coverage be as broad as its literal language indicates * * *." *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1969). Thus the Act has been held to apply to situations where drugs are held by retailers, *United States* v. *Sullivan*, 332 U.S. 689, 696-697, 68 S.Ct. 331, 335-336, 92 L.Ed. 297 (1948), wholesalers, *DeFreese* v. *United States*, 270 F.2d 730 (5th Cir.1959), *cert. denied*, 362 U.S. 944, 80 S.Ct. 810, 4 L.Ed.2d 772 (1960), bailees, *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92, 84 S.Ct. 559, 563, 11 L.Ed.2d 536 (1964), and physicians, *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981). As explained by the court in *United States* v. *10 Cartons, Labeled in Part "Hoxsey"*, 152 F. Supp. 360, 365 (W.D.Pa.1957), it "is not the holding for sale in a technical legal sense which gives rise to the federal jurisdiction * * * but the fact that the channels of commerce have been used." *See also United States* v. *Sene X Eleemosynary Corp.*, 479 F.Supp. 970, 981 (S.D.Fla. 1979) ("[t]he 'held for sale' standard of section 301 has long been afforded a liberal reading").

On appeal, FDA does not focus its energies on the argument that the unapproved use of drugs for lethal injection is outside the general jurisdictional provisions of the Act. Instead, FDA argues that state-sanctioned use of lethal injections comes within a commonly recognized

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[12] See note 37 *infra*.

exception to the Act's broad and protective coverage: the "practice-of-medicine" exemption. FDCA's legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine.[13] According to the Commissioner, FDCA does not regulate physicians in their practice because physicians are licensed by the states. Letter from the Commissioner at 3, JA 88. Since state prisons are also licensed by the states, the Commissioner thought that FDA did not have jurisdiction to regulate the use of drugs in capital punishment systems. *Id* at 2-3, JA 87-88.

The problem with the Commissioner's analogy is his starting point: that the practice of medicine is exempt because physicians are licensed by the states. There is scant legislative history on the subject,[14] but the few sentences that can be found are more fairly read as reflecting Congress' recognition that the states *do* regulate the practice of medicine and that a physician *cannot* be eligible for the practice-of-medicine exemption if he has not been so licensed. The practice-of-medicine

[13] The first bill to pass either house of Congress that was substantially similar to the present Act included within its definition of "drug" the qualification that it did not apply to "the regulation of the legalized practice of the healing art." S. 5, 74th Cong., 1st Sess. § 201(b), 79 Cong. Rec. 8351 (1935). In explaining this proviso the committee reports emphasized that the bill was "not intended as a medical practices act and [would] not interfere with the practice of the healing art by chiropractors and others in the States where they are licensed by law to engage in such practice." S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935); S.Rep. No. 646, 74th Cong., 1st Sess. 1 (1935). While the definition of "drug" as ultimately enacted did not include this proviso, *see* 21 U.S.C. § 321(g) (1976), the legislative history makes clear that Congress did not want to limit a physician's ability to treat his patients.

[14] *See* S.Rep. No. 361, *supra* note 13, at 3, 5; S.Rep. No.646, *supra* note 13, at 1, 2.

exemption itself, however, cannot be attributed to the states' licensing of their physicians.

The better explanation for the practice-of-medicine exemption is that Congress did not want to interfere with physicians' treatment of their patients. New uses for drugs are often discovered after FDA approves the package inserts that explain a drug's approved uses. Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses.[15] Thus Congress exempted the practice of medicine from the Act so as not to limit a physician's ability to treat his patients.[16]

[15] The "new drug" provisions of FDCA require the filing of a new drug application, including full reports of investigations with respect to the drug's safety and effectiveness; a full list of the articles used as components of the drug; a full statement of the composition of the drug; a full description of the methods used in, and the facilities and controls used for, the manufacturing processing, and packing of such drugs; samples of the drugs and the articles used as components; and specimens of the labeling proposed to be used. 21 U.S.C. § 355(b). An applicant may have to wait up to six months for action and participate in hearings. *Id.* § 355(c) & (c)(2). Hence, these "new drug" provisions simply do not fit the reality of the clinical situation.

[16] The case law under this and related statutes is consistent with our reading of the legislative history. *See United States* v. *Evers*, 643 F.2d 1043, 1044 (5th Cir.1981) (physician does not misbrand when he administers drug to his own patients); *see also United States* v. *Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975) (physician violates related law when he sells illicit drugs to addicts); *United States* v. *Collier*, 478 F.2d 268 (5th Cir.1973) (physician using drugs is outside the scope of the practice of medicine).

Indeed, FDA's prior interpretation of the relevant legislative history matches our own.

> Throughout the debate leading to enactment [of the Act], there were repeated statements that Congress did not in-

If FDA were correct that physicians' use of drugs is not within FDA's jurisdiction simply because physicians are licensed by the states, then it would necessarily follow that FDA could have no authority to regulate drugs that state-licensed physicians administer to prison inmates in experimental clinical investigations and no authority to regulate drugs that state-licensed veterinarians use to put animals to their death. But FDA has in fact regulated drugs used in prison clinical investigations, *see* 21 C.F.R. § 50.44 (1983), and in veterinary practices, *see United States* v. *Beauthanasia-D. Regular*, [1979 Transfer Binder] Food Drug Cosm.L.Rep. (CCH) ¶ 38265 (D. Neb.1979). In both situations FDA has rejected arguments that it does not have authority to regulate unapproved uses of approved drugs.[17] Nonmedical use of lethal injections therefore cannot fall within the "practice-of-medicine" exemption simply because the states license their prison facilities.[18]

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tend the Food and Drug Administration to interfere with medical practice and references to the understanding that the *bill did not purport to regulate the practice of medicine as between the physician and the patient.* Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

Policy Statement, 37 Fed. Reg. at 16503 (emphasis added).

[17] *See Protection of Human Subjects; Prisoners Used as Subjects in Research*, 45 Fed. Reg. 36388 (May 30, 1980) (rejecting argument in context of drug investigations with state prisoners); Answer of Defendant in D.D.C. Civil Action No. 81-2265, at ¶ 20, JA 91 (admitting that FDA has previously taken the position that new drug applications demonstrating the safety and effectiveness of chemicals used to put dogs to sleep must be filed).

[18] FDA's contention that the Act embodies congressional deference to state law in "several other respects" is further evi-

FDA did suggest cursorily in both its brief on appeal, brief for appellee at 26 n. 25, and its initial Letter from the Commissioner, JA 86-88, that the use of drugs for lethal injections, even if not covered by the practice-of-medicine exception, falls outside the jurisdictional ambit of the FDCA. The dissent to this opinion has graciously elaborated FDA's alternative argument; while acknowledging the inapplicability of the practice-of-medicine exception, the dissent argues that "FDA jurisdiction depends upon the existence of misbranding under § 331(k), which cannot be established under the facts of this case." Dissent at 1198.

Section 331(k) prohibits any action taken upon a "food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." 21 U.S.C. § 331(k). The dissent contends that no misbranding could have occurred in the present

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dence of its misreading of congressional intent. FDCA is based upon the Commerce power, and the fact that the Act does not apply to wholly intrastate activity simply reflects the limits of Congress' powers, not deference to all state-mandated activity. Likewise, FDA's claim that "the Act generally defers to state law in areas that do not directly conflict with it," brief for appellee at 18, is a curious way of stating the obvious proposition that a state may at times regulate in areas in which Congress has elected not to regulate. But the Supremacy Clause of the Constitution still preempts any state law, like a lethal injection statute, that conflicts with federal law. *See Arkansas* v. *Kansas & Texas Coal Co.*, 183 U.S. 185, 189, 22 S.Ct. 47, 48, 46 L.Ed. 144 (1901). And the Supreme Court has concluded that FDCA should be read broadly, even if doing so "would result in far-reaching inroads upon customary control by local authorities of traditionally local activities * * *." *United States* v. *Sullivan*, 332 U.S. 689, 693, 68 S.Ct. 331, 334, 92 L.Ed. 297 (1948).

case because the drugs that prisons hold for use in lethal injections cannot be deemed to be "held for sale" under any "conceivable interpretation of the English language." Dissent at 1199.

This rhetorical flourish masks what is in essence a "plain meaning" argument, and we do not fulfill our interpretive role when we look only to the statutory language. Inquiry into the statutory scheme and legislative history of the FDCA and subsequent amendments reveals a specific congressional intent to prevent misbranding of drugs at each stage of the distribution process from manufacturer to patient. *Accord United States* v. *Evers*, 643 F.2d 1043, 1049 (5th Cir.1981). In the first place, Section 331(b) of the FDCA, which prohibits any misbranding in "interstate commerce," should be sufficiently broad to cover the actions of the state prisons in this case, given the modern constitutional understanding of the breadth of congressional power under the commerce clause. Moreover, Congress enacted the "held for sale" provision of Section 331(k), on which the dissent relies, to expand, not to limit, the ambit of the FDCA. Prior to addition of this language in 1938, the FDCA had been open to an interpretation, under the more restrictive reading of the phrase "interstate commerce" then prevailing, that excluded from the Act's coverage the penultimate actor in the distribution chain if that entity had neither received nor transmitted a misbranded drug in interstate commerce. Filling this potential gap in the statute's protective scheme, Congress enacted Section 331(k) with the specific and explicitly stated intent to "extend the protection of consumers contemplated by the law to the full extent constitutionally permissible." H.R. Rep. No. 2139, 75th

Cong., 3d Sess. 3 (1938). The drugs that states use have moved through the channels of interstate commerce, *see* Memorandum in Support of Defendant's Motion to Dismiss at 15, JA 141, and Congress thus is well within its constitutional powers when it seeks to regulate the use to which these drugs are put. In light of Congress' express intent to exercise these powers to the hilt in Section 331(k), it would be both ironic and impermissible for this court to construe that section so as to limit FDA's jurisdiction in this case.[19]

In apparent recognition of the broad scope of the term "held for sale," the dissent must strain to argue that Section 331(k) nonetheless does not apply because the prison officials in this case are not the penultimate actors at whom this section is aimed, but rather the ultimate consumers of the drug and thus beyond the strictures of the Act. This view blinks reality. The ultimate consumer is not the last person to purchase the drug, but the last person to *consume* the drug—usually a patient, as *United States* v. *Evers*, notes, 643 F.2d at 1049, but in this case the prisoner who receives the lethal injection. That the prisoner might be an unwilling consumer does not change the fact that the prisoner is the one who will suffer an excruciating death if this unapproved administration is conducted improperly. Styling the ultimate purchaser as the ultimate con-

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[19] *Accord United States* v. *Sene X Eleemosynary Corp.*, 479 F.Supp. 970, 981 (S.D. Fla. 1979) ("[t]he 'held for sale' standard of section 301 [29 U.S.C. § 331] has long been afforded a liberal reading"); *United States* v. *10 Cartons Labeled in Part "Hoxsey"*, 152 F.Supp. 360, 365 (W.D.Pa.1957) (it "is not the holding for sale in a technical legal sense which gives rise to the federal jurisdiction * * * but the fact that the channels of commerce have been used.").

sumer, the dissent would free from the strictures of the FDCA any use to which the purchaser wished to put the drugs. Such a reading thwarts the ultimate purpose of Section 331 of the FDCA—protection of those who consume drugs from the potential harm of misbranding by anyone in the chain of distribution.[20]

FDA admits that it has jurisdiction over all state laws "that purport[ ] to legitimize the lawful shipment of an unapproved drug in interstate commerce, or that purport[ ] to permit its misbranding after shipment * * *." Brief for appellee at 20 n. 21. The states' lethal injection statutes purport to mandate the use of certain prescription drugs for a purpose not

[20] *United States* v. *Evers*, *supra* note 16, does not support a restrictive reading of the "held for sale" language in this case. In *Evers* the court held that a physician did not violate the FDCA when he held certain approved drugs for treatment of his patients and simultaneously advertised and advocated a treatment program that involved an unapproved use of those drugs. Although the physician had both held drugs for sale and advocated unapproved use of the drugs without proper instructions, the court found no violation on the basis of the unique facts of the case. The persons for whose benefit the physician held the drugs—his patients—were not the persons to whom the physician owned the statutory duty to give adequate instructions. The practice-of-medicine exception exempted the physician from the duty not to advocate an unapproved use to his patients. The duty ran to other physicians who might hear his advertisement of the unapproved treatment process and might therefore use the drugs without adequate instructions. Thus the physician neither "held for sale" to the doctors to whom he owed a statutory duty not to misbrand, nor owed a duty to the patients to whom he "held for sale." Under these unique facts, no violation was made out.

Evers is clearly distinguishable from the present case. In this case the persons to whom the prisons owe a statutory duty are the same persons for whom the prisons hold the drugs for sale—the prisoners. The FDA cannot, under these circumstances, succeed in its claim that it lacks jurisdiction.

listed on their label. The activity of the states falls within the jurisdictional ambit of Section 331 of the FDCA, and the practice-of-medicine exception does not immunize this activity from the FDCA's prohibition of misbranding. FDA therefore must have jurisdiction to regulate such activity.[21]

III. ENFORCEMENT DISCRETION

Of course, FDA determined that even if it had jurisdiction it would choose, in its inherent enforcement discretion, not to investigate or to take any regulatory action. Letter from the Commissioner at 3, JA 88. The District Court held both that FDA's decision to refrain from investigation and enforcement was unreviewable and that, in any event, the decision did not amount to a complete abdication of statutory responsibility. Dist.Ct.Op. at 10-15, JA 224-229. We find that the District Court misunderstood and misapplied its review authority.

A. Judicial Review of Enforcement Discretion

Section 10 of the Administrative Procedure Act (APA), 5 U.S.C. § 701(a) (1982), governs judicial re-

[21] FDA's determination that it does not have jurisdiction over drugs used in lethal injections is entitled to only the most limited deference because it is inconsistent with longstanding FDA and court interpretation of the Act. *See FEC* v. *Democratic Senatorial Campaign Committee*, 454 U.S. 27, 37, 102 S.Ct. 38, 44, 70 L.Ed.2d 23 (1981); *Zenith Radio Corp.* v. *United States*, 437 U.S. 443, 450, 98 S.Ct. 2441, 2445, 57 L.Ed.2d 337 (1978). Where an agency's interpretation contradicts the express language and purpose of a statute, courts give that interpretation little deference. *See, e.g., FPC* v. *Conway Corp*, 426 U.S. 271, 279, 96 S.Ct. 1999, 2004, 48 L.Ed.2d 626 (1976); *Office of Consumers' Counsel* v. *FERC*, 655 F.2d 1132, 1141-1142 (D.C.Cir.1980); *Elizabethtown Gas Co.* v. *FERC*, 575 F.2d 885, 887-889 (D.C.Cir. 1978).

view of agency action. Under Section 10, all final agency action is subject to judicial review unless such review is precluded by statute or committed to agency discretion by law. 5 U.S.C. § 701(a)(1) & (2).[22] This section establishes a "strong presumption" of reviewability, and the exceptions of 5 U.S.C. § 701(a)(1) & (2) should therefore be construed narrowly. *See Dunlop* v. *Bachowski*, 421 U.S. 560, 567 & n. 7, 95 S.Ct. 1851, 1858 & n. 7, 44 L.ED.2d 377 (1975); *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 410, 91 S.Ct. 814, 820, 28 L.Ed.2d 136 (1971); *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 140-141, 87 S.Ct. 1507, 1510-1512, 18 L.Ed.2d 681 (1967); *WWHT, Inc.* v. *FCC*, 656 F.2d 807, 809, 815 (D.C.Cir. 1981); *Natural Resources Defense Council, Inc.* v. *SEC*, 606 F.2d 1031, 1043 (D.C.Cir.1979).[23]

[22] The APA defines "agency action" to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent *or denial thereof, or failure to act*," 5 U.S.C. § 551(13) (1982) (emphasis added), and gives courts the power to "compel agency action unlawfully withheld or unreasonably delayed," *id* § 706(1). Thus the APA authorizes courts to review agency decisions to *refrain* from taking action. *See, e.g., Dunlop* v. *Bachowski*, 421 U.S. 560, 95 S.Ct. 1851, 44 L.Ed.2d 377 (1975) (explicitly approving review of decision of Secretary of Labor not to file suit to invalidate union election); *WWHT, Inc.* v. *FCC*, 656 F.2d 807 (D.C.Cir.1981) (reviewing FCC denial of petition to institute rulemaking proceedings); *Carpet, Linoleum & Resilient Tile Layers, Local Union No. 419* v. *Brown*, 656 F.2d 564 (3d Cir.1974) (requiring FHA to make reasonable efforts to ascertain whether homes with insured mortgages meet municipal housing code standards); *Adams* v. *Richardson*, 480 F.2d 1159 (D.C.Cir.1973) (*en banc*) *(per curiam)* (requiring HEW to commence enforcement proceedings against certain segregated school districts and systems); *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1971) (requiring Secretary of Agriculture to cancel registration of DDT by issuing cancellation notices).

[23] The dissent claims that these cases, or at least the portions cited, do not involve the committed-to-agency-discretion exception of 5 U.S.C. § 701(a)(2), which is at issue in this case, but rather the precluded-by-statute exception of § 701(a)(1), which is not. *See* Dissent at 1193. This claim is flatly inaccurate. In *Natural Resources Defense Council, Inc.* v. *SEC*, 606 F.2d 1031 (D.C. Cir. 1979), Judge McGowan's opinion, at page 1043, states that both § 701(a)(1) and § 701(a)(2) create a "strong presumption of reviewability." Later on the same page the opinion reiterates the point with respect to § 701(a)(2), noting that it applies only "in rare instances." *Id.* And on the following page the opinion articulates a test for deciding whether an action is committed to agency discretion under § 701(a)(2) that requires an inquiry as to "whether the considerations in favor of nonreviewability * * * are sufficiently compelling to rebut the strong presumption of judicial review." *Id.* at 1044. Similarly, both *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967), and *WWHT, Inc.* v. *FCC*, 656 F.2d 807 (D.C. Cir.1981), held, on the pages cited in this opinion, that the APA created a strong presumption of reviewability in the context of a discussion of both § 701(a)(1) and § 701(a)(2). 387 U.S. at 140-141, 87 S.Ct. at 1510-1511; 656 F.2d at 809 (citing the very page in *Natural Resources Defense Council, Inc.* v. *SEC*, *supra*, cited in this opinion, 606 F.2d at 1043); *see also WWHT, Inc.* v. *FCC*, *supra*, 656 F.2d at 815 (discussing the issue in more detail and making clear that it is a § 701(a)(2) case). The dissent, moreover, contradicts itself on precisely this point when it later acknowledges that *"Natural Resources Defense Council* states that the *totality* of § 701(a) * * * creates a 'strong presumption of reviewability,' 606 F.2d at 1043. Undoubtedly so." Dissent at 1195 (emphasis in original).

More importantly, the neat demarcation that the dissent seeks to draw between the precluded-by-statute and committed-to-agency-discretion exceptions to review tends to muddy the analysis in this area. Under § 10 claims of nonreviewability are disfavored, whatever their source. The Supreme Court's analysis in *Abbott Laboratories* v. *Gardner*, *supra*, is instructive. In deciding whether pre-enforcement review of an FDA regulation was appropriate, the Court noted that "a survey of our cases shows that judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe such was the purpose of Congress," 387 U.S. at 140, 87 S.Ct. at 1511, went on to point out that the "Adminis-

Neither FDA nor the District Court claims that FDCA precludes judicial review.[24] Rather, both assert that FDCA gives FDA *absolute* discretion over decisions concerning investigation and enforcement, Letter from the Commissioner at 3, JA 88; Dist.Ct. Op. at 10, JA 24, and thus commits those decisions to agency dis-

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trative Procedure Act * * * embodies the basic presumption of judicial review so long as no statute precludes such relief or the action is not one committed by law to agency discretion, *Id.*, and concluded that "only upon a showing of 'clear and convincing evidence" of a contrary legislative intent should the courts restrict access to judicial review." *Id* at 141, 87 S.Ct. at 1511 (*quoting Rusk* v. *Cort*, 369 U.S. 367, 82 S.Ct. 787, 7 L.Ed.2d 809 (1962)). One important question we must ask, therefore, is whether Congress intended to grant FDA unreviewable power in the enforcement area. We find no evidence of such an intention in this case.

The dissent also seeks to deflect the force of the principle stated in *Natural Resources Defense Council*, *supra*, and *WWHT, Inc.*, *supra*, with the argument that these cases are inapposite to the present controversy because they involved the reviewability of rulemaking, not enforcement, decisions. *See* Dissent at 1194-1195. But it is the dissent that misses the mark. We do not rely on these cases to support the proposition that because rulemaking decisions can be reviewed enforcement decisions perforce can be reviewed. Rather, we simply follow the consistent construction of § 10 of the APA articulated in *Natural Resources Defense Council* and *WWHT, Inc.* This consistent construction establishes a strong presumption of reviewability in cases under § 10. The courts in *Natural Resources Defense Council* and in *WWHT, Inc.* evaluated the reviewability of the rulemaking decisions at issue in light of this strong presumption. Similarly, we take cognizance of the strong presumption as we undertake our evaluation of the reviewability of the exercise of enforcement discretion at issue in the present case.

[24] The statute has detailed provisions that specifically contemplate judicial review. *See, e.g.*, 5 U.S.C. § 332(a) (jurisdiction of courts over injunction actions); *id.* § 346a(i) (judicial review of regulations which establish tolerances for pesticide chemicals); *id* § 348(g) (judicial review for controversies over food additives); *id.* § 355(h) (judicial review of new drug orders); *id* § 360(g) (judicial review of premarketing provisions).

cretion by law. 5 U.S.C. § 701(a)(2). Though some courts have traditionally displayed reluctance to review exercises of enforcement discretion, the Supreme Court has consistently instructed us to construe narrowly the "committed to agency discretion" exception, and to find it applicable only in those rare instances where the governing statute is "drawn in such broad terms that in a given case there is no law to apply." *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, *supra*, 401 U.S. at 410, 91 S.Ct. at 821, *quoting* S.Rep. No. 752, 79th Cong., 1st Sess. 26 (1945).[25] This admonishment applies

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[25] The dissent makes light of the importance of *Overton Park* to the resolution of this controversy. Dissent at 1193. *Overton Park* must, however, occupy a central place in our analysis: it defines the meaning of the committed-to-agency-discretion exception of § 701(a)(2) that is at issue here. To dilute the power of the Court's command that we give § 701(a)(2) an extremely narrow construction, 401 U.S. at 410, 91 S.Ct. at 820, the dissent argues that "[u]nless one assumes that the Supreme Court was casually setting forth a rule wildly out of accord with prior case law, the obvious meaning of 'narrow construction' was an application that would limit the exception to enforcement discretion and to a few other matters * * *." Dissent at 1193. Apparently the Supreme Court missed this "obvious meaning" in 1975 when the Court cited the relevant page of *Overton Park* to support its holding in *Dunlop* v. *Bachowski*, *supra* note 22, 421 U.S. at 567, 95 S.Ct. at 1857, that the Secretary of Labor's exercise of enforcement discretion was reviewable. The constricted reading of *Overton Park* is also difficult to square with the text of *Overton Park* itself; the opinion does not even hint at the meaning that the dissent would divine from it, but stresses that the § 701(a)(2) exception is "very narrow" and is to be applied in "rare instances." 401 U.S. at 410, 91 S.Ct. at 820. Moreover, the Court cited as direct support for its holding an article by Raoul Berger in which he specifically discusses and approves review of agency enforcement discretion. Berger, *Administrative Arbitrariness and Judicial Review*, 65 Colum. L. Rev. 55, 68 (1965).

with no less force to review of agency enforcement discretion, including agency decisions to refrain from enforcement action. *Dunlop* v. *Bachowski*, *supra*, 421 U.S. 560, 95 S.Ct. 1851, 44 L.Ed.2d 377.

The *Dunlop* case deserves close scrutiny because it held, on facts precisely analogous to those of the present case, that an agency decision not to exercise enforcement discretion was reviewable. In *Dunlop* an unsuccessful candidate for a union office complained to the Secretary of Labor that the election was fraudulent, and thus invoked 29 U.S.C. § 482, a provision of the Labor-Management Reporting and Disclosure Act that empowers the Secretary to investigate such complaints and to bring a civil action to set aside the election if warranted. 421 U.S. at 562-563, 95 S.Ct. at 1855-1856. The Secretary took no action in response to the complaint in *Dunlop*, and the unsuccessful union candidate sought review of that decision to refrain from exercising enforcement power. The Secretary argued that his action was unreviewable under Section 10 of the APA, and relied on both the precluded-by-statute and the committed-to-agency-discretion exceptions of Section 10 of the APA. 5 U.S.C. § 701(a)(1) & (2). Finding neither exception applicable, 421 U.S. at 567 & n. 7, 95 S.Ct. at 1858 & n.7, the Court held that this discretionary decision to refrain from exercising enforcement power was reviewable.[26] In the present con-

[26] The Court in *Dunlop* explicitly rejected the Secretary's claim that the nonenforcement decision was an unreviewable exercise of prosecutorial discretion, and expressly adopted the reasoning of the lower court on this point. 421 U.S. at 567 n. 7, 95 S.Ct. at 1858 n. 7. The Circuit Court, in *Bachowski* v. *Brennan*, 502 F.2d 79 (3d Cir.1974), had advanced two rationales for holding that the Secretary's decision should not be viewed as unreviewable prosecutorial discretion. First, "the doctrine of prosecutorial discretion should be limited to those civil cases which, like criminal prosecutions, involve the vindication of societal or governmental interest, rather than the protection of individual rights." 502 F.2d at 87. Second, appropriate legal standards existed against which the Secretary's conduct could be measured. *Id.* at 88.

These considerations apply with equal force to the present controversy. The FDCA provisions are intended not only to protect the general welfare, but also specifically to protect the individuals on whom drugs are used. Since appellants in this case are involuntary users of the drugs, they stand in a position analogous to the unsuccessful union official in *Bachowski* v. *Brennan;* if the agency refuses to act, appellants are left unprotected. 502 F.2d at 87-88. "Absolute discretion in this situation seems particularly inappropriate." *Id.* Moreover, clear legal standards exist against which the agency action at issue can be measured; in the words of *Overton Park*, there is "law to apply." See notes 27 & 28 and accompanying text *infra*.

To blunt the precedential force of *Bachowski* v. *Brennan*, the dissent mischaracterizes the holding as an exceedingly narrow one, based on extraordinary circumstances that justified departure from the usual rule disfavoring review: "The court of appeals finds it necessary carefully to distinguish the type of enforcement resonsibility given the Secretary under the L-MRDA from the more typical case in which a decision not to enforce is unreviewable. * * * Thus *Dunlop* reaffirms the principle of general unreviewability of enforcement decisions." Dissent at 1193. The Court of Appeals in *Bachowski*, of course, intended just the opposite. The opinion takes pains to limit the applicability of notions of deference to prosecutorial discretion in the area of review of agency enforcement decisions. No language in the opinion even hints that the court viewed the case before it as atypical or extraordinary in any way. Nor does any language in the opinion state or even imply that the court acknowledged a general presumption against review; only with the addition of italics does the language quoted in the dissent even begin to hint at such a meaning. *See* Dissent at 1193.

troversy appellants seek nothing more than what the disappointed union official sought in *Dunlop:* judicial review of an agency decision not to exercise enforcement power. *Dunlop* thus precludes a facile resolution

denying review in this case because an exercise of enforcement discretion is at issue. We must, under the test of *Overton Park*, decide whether there is "law to apply" to FDA's nonenforcement decision in this case.

The determination of whether there "is law to apply" turns on such pragmatic considerations as whether judicial supervision is necessary to safeguard plaintiffs' interests, whether judicial review will unnecessarily impede the agency in effectively carrying out its congressionally assigned role, and whether the issues are appropriate for judicial review. *Natural Resources Defense Council, Inc.* v. *SEC*, *supra*, 606 F.2d at 1043-1044. We conduct this inquiry to determine whether the considerations favoring nonreviewability are sufficiently compelling to rebut the strong presumption of judicial review. *Id.* In this case, however, we need not delve into a detailed analysis of nonreviewability because the agency has already conducted the inquiry for us. FDA, in an earlier policy statement, made law to govern and guide its discretion in regulating the unapproved use of approved drugs:

> Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. * * * When necessary the Food and Drug Administration will not hesitate to take whatever action * * * may be required to bring possible harmful use of an approved drug under control.
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> * * * Thus, where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly.

Policy Statement, 37 Fed.Reg. at 16504. This policy statement which FDA still considers binding and to have substantive effect, *see* Memorandum in Support of Motion to Dismiss at 4-5 & nn. 10,12, JA 131-132, comes within the APA's definition of a rule[27] as that term has been consistently interpreted in this circuit. The term "rule" is "broad enough to include nearly every statement an agency may make * * *'" *Center for Audto Safety* v. *NHTSA*, 710 F.2d 842, 846 (D.C.Cir.1983), *quoting Batterton* v. *Marshall*, 648 F.2d 694, 700 (D.C.Cir.1980). In *Center for Auto Safety* the court concluded that agency policy statements accompanying the withdrawal of a notice of proposed rulemaking fell within the definition of "rule" because they "clearly interpret the relevant statute and indicate NHTSA's policy regarding the exercise of discretion granted to it by that legislative enactment." 710 F.2d at 846. The FDA policy statement quoted above also interprets the relevant statute and indicates FDA's policy regarding the exercise of its discretion.[28] The

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[27] *See* 5 U.S.C. § 551(4) (1982) (a "'rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement * * * law or policy"). An agency statement that is binding and that has substantive effect is a rule. *See Guardian Federal S. & L. Ass'n* v. *Federal S. & L. Ins. Corp.*, 589 F.2d 658, 666-669 (D.C. Cir. 1978); *Pickus* v. *United States Board of Parole*, 507 F.2d 1107, 1112-1113 (D.C. Cir. 1974).

[28] That the Policy Statement accompanied an unadopted rule is not decisive. FDA has admitted that the Policy statement is an authoritative statement of agency views as to what the stat-

policy statement, along with the precise terms of the statute[29] and a growing body of case law,[30] thus provides this court with more than enough law to apply.[31] Where a court has "law to apply" agency action is *not* committed to agency discretion and *is* subject to judicial review under the APA. *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, *supra*, 401 U.S. at 410, 91 S.Ct. at 820.

The District Court did not review the APA's provisions governing judicial review or discuss the case law

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ute under which it operates requires. Memorandum in Support of Motion to Dismiss at 4-5 & nn. 10, 12, JA 131-132; Letter from the Commissioner at 2, JA 87. This admission, moreover, eviscerates any potential argument that FDA renounced the guidelines in the policy statement when it withdrew the proposed rule that accompanied the statement. The withdrawal indicates not that FDA rejected the contents of the policy statement, but only that FDA decided that the proposed rule was not a preferred method of putting the policy goals into effect.

[29] See notes 1-3, 24 *supra* and accompanying text. FDCA's prohibitions are phrased in mandatory terms. *See, e.g.*, 21 U.S.C. § 333(a) (any person who violates § 331 "shall" be imprisoned or fined); *id.* § 336 (at minimum, Secretary must provide suitable written notice or warning of minor violations). The statute's legislative history indicates that Congress intended for courts to review and to grant appropriate relief against "any act or omission on the part of the Department in the administration of the act." S.Rep. No. 646, *supra* note 13, at 10.

[30] *See, e.g., United States* v. *Evers*, supra note 16; *United States* v. *Beuthanasia-D. Regular*, *supra* note 5; *Hoffman-LaRoche, Inc.* v. *Weinberger*, 425 F. Supp. 890 (D.D.C. 1975); *American Public Health Ass'n* v. *Veneman*, 349 F.Supp. 1311 (D.D.C. 1972).

[31] 2 K. DAVIS, ADMINISTRATIVE LAW TREATISE §§ 7:26-7:28, 28:16 (2d ed. 1979 & 1982 Supp.) It is a well established precept that courts can review agencies for conformance to their rules and regulations, especially where those rules are to have substantive effect. *See Service* v. *Dulles*, 354 U.S. 363, 77 S.Ct. 1152, 1 L.Ed.2d 1403 (1957); *United States ex rel. Accardi* v. *Shaughnessy*, 347 U.S. 260, 74 S.Ct. 499, 98 L.Ed. 681 (1954).

establishing the strong presumption of reviewability. Rather, it relied on cases articulating the venerable proposition that courts should not unduly interfere with prosecutorial discretion.[32] But this proposition has never been blindly applied: "[T]he decisions of this court have never allowed the phrase 'prosecutorial discretion' to be treated as a magical incantation which automatically provides a shield for arbitrariness." *Medical Committee for Human Rights* v. *SEC*, 432 F.2d 659, 673 (D.C.Cir.1970), *vacated as moot*, 404 U.S. 403, 92 S.Ct. 577, 30 L.Ed.2d 560 (1972).[33] Indeed, in the last twenty years federal courts have frequently forced agencies to implement and enforce their regulatory

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[32] Dist.Ct.Op. at 10-11, JA 224-225. The judicial reluctance to interfere with prosecutorial discretion arises from the lack of specific action to review, the lack of a record, separation of powers principles, the prosecuting agency's need to control its own resources, solicitude for the accused, and adverse effects on voluntary settlement. But both courts and commentators have convincingly demonstrated that these concerns do not justify committing agency enforcement action completely to administrative discretion or totally precluding judicial review. *See Dunlop* v. *Bachowski*, *supra* note 22, 421 U.S. at 571-572, 95 S.Ct. at 1859-1860; *Adams* v. *Richardson*, *supra* note 22, 480 F.2d at 1161-1163; 2 K. Davis, *supra* note 31, §§ 9:1-9:6 at 215-248; Vorenberg, *Decent Restraint of Prosecutorial Discretion*, 94 Harv. L. Rev. 1521, 1545-1554 (1981); Note, *Judicial Review of Administrative Inaction*, 83 Colum. L. Rev. 627, 630-645, 658-661 (1983).

[33] *See, e.g., Marshall* v. *Jerrico, Inc.*, 446 U.S. 238, 249-250, 100 S.Ct. 1610, 1616-1617, 64 L.Ed.2d 182 (1980) (reviewing claim that administrator had personal interest in outcome); *Yick Wo* v. *Hopkins*, 118 U.S. 356, 6 S.Ct. 1064, 30 L.Ed. 220 (1886) (reviewing claim that law was discriminatorily applied); *see also Blackledge* v. *Allison*, 431 U.S. 63, 76, 97 S.Ct. 1621, 1630, 52 L.Ed.2d 136 (1977) (reversing conviction on ground that prosecutor did not keep a promise).

statutes, or at least to explain their failure to do so.[34] While the cases the District Court cited are distinguishable from the case at bar,[35] the real "key lies in recog-

[34] See note 22 *supra*.

[35] *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 138, 95 S.Ct. 1504, 1510, 44 L.Ed.2d 29 (1975), and *Vaca* v. *Sipes*, 386 U.S. 171, 182, 87 S.Ct. 903, 912, 17 L.Ed.2d 842 (1967), both hold, in dicta, that the General Counsel of the National Labor Relations Board has unreviewable discretion to refuse to initiate an unfair labor practice complaint. *Sears Roebuck* makes clear, however, that this agency discretion was unreviewable as a result of the explicit preclusive statutory command of 29 U.S.C. § 153(d), 421 U.S. at 138, and not as a result of any generalized presumption against review of agency enforcement discretion. Also, unreviewable enforcement discretion arises only under statutes which, unlike the FDCA, are *not* for the benefit of individuals, but only for the country as a whole. *See Bachowski* v. *Brennan*, *supra* note 26, 502 F.2d at 87 & n. 11, *rev'd on other grounds, but cited with approval on this point, Dunlop* v. *Bachowski*, *supra* note 22, 421 U.S. at 567 n. 7, 95 S.Ct. at 1858 n. 7. *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411, 414, 78 S.Ct. 377, 380, 2 L.Ed.2d 370 (1958), simply held that the Federal Trade Commission's discretionary determinations to prosecute should "not be overturned in the absence of a patent abuse of discretion." *SEC* v. *Tiffany Industries, Inc.*, 535 F.Supp. 1160 (E.D.Mo. 1982), simply did not involve judicial review of the propriety of an agency's exercise of enforcement discretion. *Newman* v. *United States*, 382 F.2d 479 (D.C.Cir. 1967), involved the prosecutorial discretion of a United States Attorney in a criminal matter, a discretion that has always received the maximum degree of judicial deference.

Kixmiller v. *SEC*, 492 F.22d 641 (D.C.Cir. 1974), will not bear the weight of the assertion, made by the District Court and echoed in the dissent to this opinion, that the case supports a strong presumption against reviewability. The language at 644-645 of 492 F.2d, on which the District Court and the dissent rely, is most fairly read as holding that review is statutorily precluded on the facts of *Kixmiller*. And the three authorities that *Kixmiller* cites for its overbroad dictum that agency enforcement discretion is "generally unreviewable," 492 F.2d at 645 & n. 27, will not support such a position. The first, *Goldberg* v. *Hoffman*, 225 F.2d 463, 466 (7th Cir. 1955), involved not agency discretion but the pure prosecutorial discretion of a

nizing that the law has been in transition and that the case law * * * [is now] strongly on the side of reviewability." 2 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 9:6, at 239-240 (2d ed. 1979).[36]

United States Attorney in a criminal matter. The second and third cases, *Vaca* v. *Sipes*, *supra*, 386 U.S. at 182, 87 S.Ct. at 912, and *Jacobsen* v. *NLRB*, 120 F.2d 96, 99 (3d Cir. 1941), both involved the enforcement discretion of the General Counsel of the NLRB that was later clarified by *Sears Roebuck*, *supra*, as being *statutorily* placed beyond judicial review, 421 U.S. at 138, 95 S.Ct. at 1510. Beyond these nonsupportive citations, the *Kixmiller* opinion provides no analysis to justify its posture of all but total deference to agency enforcement discretion. Most importantly, the limiting presumption stated in *Kixmiller* retains little force in light of subsequent decisions of this circuit, *see Natural Resources Defense Council, Inc.* v. *SEC*, *supra* note 30, 606 F.2d at 1043-1044, and of the Supreme Court, *see Dunlop* v. *Bachowski*, *supra* note 22, 421 U.S. at 567 & n. 7, 95 S.Ct. at 1858 & n. 7.

Moreover the two FDCA cases that the District Court cited do not hold that courts cannot review FDA's complete refusal to investigate and regulate an entire class of drugs. In *Nat'l Milk Producers Federation* v. *Harris*, 653 F.2d 339 (8th Cir.1981), the court reviewed and accepted FDA's reasons—good faith budgetary constraints—for not seeking to enforce certain regulations. *Id.* at 342. In *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C.1979), the court refused on equity grounds to require FDA to take certain drugs off the market. *Id.* at 856. To the extent dicta in *Cutler* supports the broader proposition that certain FDA duties are not mandatory, and that FDA's actions cannot be reviewed, we expressly disapprove it.

[36] In light of the strong presumption favoring judicial review articulated in *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971), and *Abbott Laboratories* v. *Gardner*, *supra* note 23, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681, elaborated in this circuit in *Natural Resources Defense Council, Inc.* v. *SEC*, *supra* note 23, 606 F.2d 1031, and *WWHT Inc.* v. *FCC*, *supra* note 23, 656 F.2d 807, and specifically made applicable to enforcement discretion in *Dunlop* v. *Bachowski*, *supra* note 22, 421 U.S. 560, 95 S.Ct. 1851, 44 L.Ed.2d 377, the dissent's insistence that agency enforcement discretion is "generally unreviewable" has an anachronistic ring. *See* Dissent at 1195-1196. And the precedents on

The District Court correctly noted that the "absence of a statutory exemption for state-mandated activity does not logically compel or even suggest * * * that the Commissioner has *no* discretion to refrain from initiating requested investigative and/or enforcement proceedings * * *." Dist.Ct.Op. at 15, JA 229 (emphasis in original). But neither does it mean that the Commissioner has absolute discretion in enforcement decisions or that these decisions are insulated from judicial review. The presumption is in favor of judicial review, and nothing in this case is sufficiently compelling to rebut this presumption. We must conclude that FDA's inaction here is subject to judicial review.[37]

B. Scope of Judicial Review

When reviewing informal agency action of this type a court must conduct a "searching and careful" re-

which the dissent places primary reliance are not helpful to it. *Kixmiller* has already been demonstrated to be seriously flawed. *See* note 35 *supra*. *Curran* v. *Laird*, 420 F.2d 122 (D.C.Cir. 1969) *(en banc)*, is wholly inapposite to this case. *Curran* involved the reviewability of a decision by the Executive Branch about the composition of this nation's reserve fleet during the Vietnam war. A majority of the court held the decision to be committed to official discretion because "these decisions are inextricably intertwined with and permeated by assumptions and conclusions of national defense strategy." 420 F.2d at 131. The opinion was careful to point out that the Executive decision occurred in the context of a "national emergency," id. at 128. *Curran* not only failed to state anything remotely resembling the presumption of "general unreviewability" that the dissent would pull from it, but simply had nothing to do with the question of agency enforcement discretion.

[37] Under the APA a negative, but final, disposition of an authorized petition for agency action is a final order subject to judicial review. See 5 U.S.C. § 551(6)(1982).

view of the "whole record" to determine if the agency has been "arbitrary or capricious." *See* 5 U.S.C. § 706(2)(A) (1976); *FPC* v. *Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 331, 96 S.Ct. 579, 582, 46 L.Ed.2d 533 (1976) *(per curiam); Citizens to Preserve Overton Park, Inc.* v. *Volpe, supra*, 401 U.S. at 416, 91 S.Ct. at 823. The court must, therefore, make a "searching and careful" review of both the administrative record, particularly the uncontroverted evidence submitted by appellant, and the agency's stated reasons for its action. If upon examination the agency record does not satisfy the appropriate standard of judicial review, its action must be vacated. If FDA's inaction in this case was arbitrary, capricious, and without authority of law,[38] and our own analysis of the record leads us

[38] The District Court reviewed the statement only to determine whether FDA had completely abdicated its statutory responsibilities. *See* Dist.Ct.Op. at 15, JA 229. This kind of review is applied to agency action taken pursuant to statutes which specifically preclude judicial review. Courts undertake such review only to ensure that the agency does not flagrantly ignore specific statutory mandates. *See, e.g., Leedom* v. *Kyne*, 358 U.S. 184, 79 S.Ct. 180, 3 L.Ed.2d 210 (1958); *Hotel Employees Local No. 255* v. *Leedom*, 358 U.S. 99, 79 S.Ct. 150, 3 L.Ed.2d 143 (1958); *Office Employees Int'l Union, Local No. 11* v. *NLRB*, 353 U.S. 313, 77 S.Ct. 799, 1 L.Ed.2d 846 (1957).

By contrast, when reviewing agency action under the "arbitrary and capricious" test, courts must assure themselves that the agency "'has exercised a reasoned discretion, with reasons that do not deviate from or ignore the ascertainable legislative intent.'" *Lead Industries Ass'n, Inc.* v. *EPA*, 647 F.2d 1130, 1154 (D.C.Cir.1980) (*quoting Greater Boston Television Corp.* v. *FCC*, 444 F.2d 841, 850 (D.C. Cir. 1970), *cert. denied*, 403 U.S. 923, 91 S.Ct.2233, 29 L.Ed.2d 701 (1971)). Courts gain such assurance only by reviewing the facts relied upon, the other facts in the record, the relevant factors considered, and the available alternatives considered. *Ethyl Corp.* v. *EPA*, 541 F.2d 1, 34 (D.C.Cir.) *(en banc), cert. denied*, 426 U.S. 941, 96

to believe it was,[39] we must remand this case for appropriate action.

First, the Commissioner stated that the "scope of his legal authority" to regulate lethal injections in state capital punishment systems is "highly uncertain." Brief for appellee at 14. But this argument simply repeats his meritless contention that FDA did not have jurisdiction in the first place.[40] Moreover, it directly contradicts FDA's own policy statement, issued in 1972 and still in effect, which declares that FDA will investigate and take all necessary action to prevent the unapproved use of approved drugs. *Policy Statement*, 37 Fed. Reg. at 16504. The policy statement makes no exception for state-mandated activity, and the Commissioner must provide an acceptable explanation of why his refusal to act in this case is not in contravention of that 1972 statement.[41] So far he has not. A "good

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S.Ct.2663, 49 L.Ed.2d 394 (1976). The District Court did not, so far as we can tell, adequately explore the agency's decision to determine if it had engaged in reasoned decisionmaking.

[39] The case was decided below on a motion for summary judgment. Therefore, appellants' factual allegations that lethal injection does not cause a "quick and painless" death and that it "poses a substantial threat of torturous and unnecessary pain to persons being executed" must be assumed to be true. Complaint ¶ 18, JA 9. *See Woiston* v. *Reader's Digest Ass'n, Inc.*, 443 U.S. 157, 162 n. 5, 99 S.Ct. 2701, 2705 n. 5, 61 L.Ed.2d 450 (1979); *Bishop* v. *Wood*, 426 U.S. 341, 347 n. 11, 96 S.Ct. 2074, 2079 n. 11, 48 L.Ed.2d 684 (1976); *United States* v. *Diebold, Inc.*, 369 U.S. 654, 655, 82 S.Ct. 993, 994, 8 L.Ed.2d 176 (1962).

[40] *See* Part II *supra*.

[41] This policy statement asserted a broad responsibility to "investigate * * * and to take whatever action is warranted to protect the public." *Policy Statement*, 37 Fed.Reg. at 16504. It specifically recognized that the Act "did not purport to regulate the practice of medicine as between the physician and the patient." *Id.* at 16503. It mentioned nothing about exempting all state-licensed activity.

faith" uncertainty about legal authority may be sound reason to decline to bring enforcement proceedings, *see* brief for appellee at 15, but willful indifference is not. We do not understand how the Commissioner can assert legal authority to regulate drugs used in both state-licensed clinical investigations and state-licensed veterinary practices and not assert, *with equal confidence*, authority to regulate drugs used in state-licensed capital punishment practices.[42] It is simply irrational—and thus arbitrary and capricious—to believe that the agency has jurisdiction over the unapproved use of drugs in the former two practices but not in the latter practice.

Second, the Commissioner asserts that the use of drugs in lethal injections does not pose a "serious danger to the public health." Brief for appellee at 15. But he cites no evidence to support this proposition. Rather, he irrebuttably presumes that "duly authorized statutory enactments * * * [which further] proper State functions" cannot, as a matter of law, pose such a danger to the public. Letter from the Commissioner at 3, JA 88. This claim is remarkable in light of the uncontroverted evidence appellants submitted to FDA, which shows that drugs used in lethal injections pose a substantial threat of torturous pain to persons being executed. ROYAL COMMISSION ON CAPITAL PUNISHMENT,

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[42] The Commissioner has not asserted, at any point, that budgetary constraints would prevent FDA from investigating and taking appropriate action. While we have no occasion to address this hypothetical explanation, we do note that other courts have rejected it in situations where Congress (or the agency) has promised that action will be taken. *See, e.g., Adams* v. *Califano*, D.D.C. Civil Action No. 70-3095 (Dec. 29, 1977); *Hoffman-LaRoche, Inc.* v. *Weinberger*, *supra* note 30; *American Public Health Ass'n* v. *Veneman*, *supra* note 30.

1949-1953 REPORT (1953), Exhibit 1 to Letter to the Secretary, JA 34-40. Furthermore, this claim flies in the face of the Commissioner's admission that FDA has jurisdiction over all state laws "that purport[ ] to legitimize the lawful shipment of an unapproved new drug in interstate commerce or that purport[ ] to permit its misbranding after shipment * * *." Brief for appellee at 20 n.21. If *some* state laws can pose a "serious danger to the public health," *no* state law can be *presumed*, in the face of substantial evidence to the contrary, not to do so. Rather, FDA can rationally distinguish between laws that *do* endanger the public health and laws that *do not* only upon the basis of available evidence. In this case *all* the evidence shows that lethal injection laws *do* endanger users of drugs, and thus the public health.[43] Finally, this claim rationally cannot stand next to FDA's earlier assertions that prisoners in clinical investigations and dogs in veterinary clinics were in "serious danger" from the unapproved use of approved drugs. If drugs used in these contexts pose a "serious threat" to the public health, then certainly drugs used to kill human beings pose such a threat.[44] In

[43] We do not imply that FDA must gather evidence concerning the health effects of all alleged statutory violations to survive judicial scrutiny. We simply hold that FDA cannot irrebuttably presume that a particular practice does not pose a "serious danger to the public health" because that practice is sanctioned by state law. FDA must give rational reasons why the practice itself can be presumed to pose no danger to the public if it is to deny a petition without investigating the allegations, particularly where the petition presents substantial evidence to the contrary.

[44] On appeal government counsel contend that lethal injection statutes cannot threaten the public health because, by definition, they apply only to a small number of persons convicted of capital offenses, and such persons have extensive legal protection under other laws. *See* brief for appellee at 15-16. As a preliminary matter, we note that courts properly affirm only on the basis of the agency's reasons, and not on the subsequent rationalizations of counsel. *Burlington Truck Lines, Inc.* v. *United States*, 371 U.S. 156, 168-169, 83 S.Ct. 239, 245-246, 9 L.Ed.2d 207 (1962). But, more to the point, even government counsel's subsequent rationalizations would not make rational this response. Over 200 persons are presently subject to this alleged statutory violation, and over 900 more are potentially in danger. *See* text accompanying note 8 *supra*. Only a callous mind would claim that this is not a serious danger to public health. The claim is particularly irrational in light of FDA's regulation of clinical practices in state prisons, where an equally small number of prisoners serve as subjects in experiments. *See* 21 C.F.R. § 50.1 *et seq.* (1983). Finally, it is established doctrine that, unless Congress has specifically otherwise decided, resort to litigation on a private cause of action is not an adequate alternative to an administrative agency performing its lawful function. *See, e.g., Medical Committee for Human Rights* v. *SEC*, 432 F.2d 659, 672 (D.C. Cir. 1970), *vacated as moot*, 404 U.S. 403, 92 S.Ct. 577, 30 L.Ed.2d 560 (1972). *See also Megapulse, Inc.* v. *Lewis*, 672 F.2d 959, 970 n. 57 (D.C.Cir.1982) (discussing adequacy of alternative remedies); *Investment Co. Institute* v. *Board of Gov'rs of Fed. Reserve System*, 551 F.2d 1270, 1279-1280 (D.C.Cir.1977) (same); *Harris Stanley Coal & Land Co.* v. *Chespeake & Ohio R. Co.*, 154 F.2d 450, 453 (6th Cir.1946) (same).

short, the Commissioner presents no rational basis for concluding that lethal injections do not pose a serious health threat. Thus we must conclude that he has acted arbitrarily, capriciously, and without authority of law.[45]

[45] This conclusion is particularly compelling since FDA refused to take any action with regard to an *entire category* of allegedly prohibited activity. Courts are especially willing to review agency lassitude (or recalcitrance) of this magnitude. *See, e.g., White v. Mathews*, 559 F.2d 852 (2d Cir.1977), *cert. denied*, 435 U.S. 908, 98 S.Ct. 1458, 55 L.Ed.2d 500 (1978) (challenging general delay in processing Social Security disability appeals); *Adams* v. *Richardson, supra* note 22 (challenging HEW's policy of not enforcing Title VI of the Civil Rights Act of 1964).

III. CONCLUSION

Judge Tamm, writing for this court over a decade ago, once noted that "assertions of discretion inevitably raise questions of degree which must be appraised in the context of the relevant provisions of law and the nature of the particular action sought to be reviewed: " '[T]he question is not *whether* agency action is by law committed to agency discretion but *to what extent* agency action is so committed.'" *Medical Committee for Human Rights* v. *SEC*, *supra*, 432 F.2d at 673 (*quoting* 4 K. DAVIS, ADMINISTRATIVE LAW TREATISE 33 (1958) (emphasis by Judge Tamm). Agency enforcement decisions are inevitably based, in large measure, on factors not particularly suitable to judicial resolution, and thus courts give these decisions a great degree of deference. But courts are also responsible for ensuring that government officials do not negate or frustrate congressional enactments through bureaucratic arbitrariness. Courts must assure the public that the vast powers agencies exercise are subject to decent and civilized restraints.[46] In this case, despite expert testimony concerning the dangerousness of using barbiturates and paralytics to execute human beings, the Commissioner of FDA refused to take any investigatory or regulatory action. He provided a glib statement of reasons for the agency's inaction that cannot withstand judicial review. Hence, we must vacate the District Court's judgment in this case with instructions to order the agency to fulfill its statutory function. Both this court and the District Court must be mindful that endless litigation, particularly in this case, concerning the sufficiency of the agency's reasons would be inconsistent with the statute's goal of expeditiously pro-

[46] *See generally* Vorenberg, *supra* note 32.

tecting consumers from the alleged hazards. We must be prepared to compel FDA to take action with respect to the prayer for relief where an acceptable explanation of its inaction is not promptly forthcoming.[47]

Appellants have presented substantial and uncontroverted evidence to support their claim that execution by lethal injection poses a serious risk of cruel, protracted death. *See* ROYAL COMMISSION ON CAPITAL PUNISHMENT, 1949-1953 REPORT (1953), Exhibit 1 to Letter to the Secretary, *supra*, JA 34-40. Even a slight error in dosage or administration can leave a prisoner conscious but paralyzed while dying, a sentient witness of his or her own slow, lingering asphyxiation. *See* brief for appellants at 10-11. In light of these risks, FDA's impermissible refusal to exercise enforcement discretion over the use of drugs for lethal injection—a use well within the jurisdictional ambit of the FDCA, *see* Part II *supra*—may also implicate the Eighth Amendment's prohibition of cruel and unusual punishment.

In a civilized society, if we assume as we must that the state may take the life of a person as punishment, decency demands that the life be taken without cruelty. The Eighth Amendment embodies society's require-

[47] There is ample precedent to support the District Court in affirmatively ordering agency action. *See, e.g., Adams* v. *Richardson*, *supra* note 22, 480 F.2d at 1163-1164; *Terminal Freight Handling Co.* v. *Solien*, 444 F.2d 699 (8th Cir.1971), *cert. denied*, 405 U.S. 996, 92 S.Ct. 1252, 31 L.Ed.2d 465 (1972); *Templeton* v. *Dixie Color Printing Co.*, 444 F.2d 1064 (5th Cir. 1971); *Trailways of New England, Inc.* v. *CAB*, 412 F.2d 926 (1st Cir.1969). For other cases addressing agency inaction, *see* note 22 *supra*. The Supreme Court has not definitively addressed the issue, *see Dunlop v. Bachowski*, *supra* note 21, 421 U.S. at 575-576, 95 S.Ct. at 1861-1862, but its logic presupposes that a court can order an agency to take affirmative enforcement action. *See id.* at 592, 95 S.Ct. at 1869 (Rehnquist, J., concurring in the result in part and dissenting in part).

ment that the means of punishment not be barbarous or torturous, *see Gregg* v. Georgia, 428 U.S. 153, 167-171, 96 S.Ct. 2909, 2922-2924, 49 L.Ed.2d 859 (1976); *In re Kemmler*, 136 U.S. 436, 447, 10 S.Ct. 930, 933, 34 L.Ed. 519 (1890) ("punishments are cruel when they involve torture or lingering death"), and the Amendment gives even to those on death row the right to a punishment that is not cruel. In this case FDA is clearly refusing to exercise enforcement discretion because it does not wish to become embroiled in an issue so morally and constitutionally troubling as the death penalty. Yet this action amounts to an abnegation of statutory responsibility by the very agency that Congress has charged with the task of ensuring that our people do not suffer harm from misbranded drugs. *See* Part III-B *supra*.

Though this failure to meet statutory responsibilities is alone sufficient to invalidate the FDA's inaction in this case, we note that by failing to exercise its statutory responsibilities FDA also places serious burdens on appellants' right to a death that is not cruel. As a result of the FDA's inaction, appellants face the risk of a cruel execution and are deprived of the FDA's expert judgment as to the effectiveness of the drugs used for lethal injection, the latter fact making any direct challenge they might bring to this method of execution more difficult. Thus, even though FDA is not responsible for the execution of these prisoners, its failure to meet its statutory responsibility may well place constitutionally impermissible burdens on the Eighth Amendment rights of appellants.

Vacated and remanded.

SCALIA, Circuit Judge, dissenting:

The majority converts a law designed to protect consumers against drugs that are unsafe or ineffective for their represented use into a law not only permitting but mandating federal supervision of the manner of state executions. This implausible result is achieved by rewriting the law with regard to enforcement discretion and ignoring it with regard to FDA jurisdiction. I dissent from what seems to me a clear intrusion upon powers that belong to Congress, the Executive Branch and the states. I would affirm for the reasons set forth in the district court's opinion.

I. ENFORCEMENT DISCRETION

Even if it were correct that the Food, Drug, and Cosmetic Act makes the challenged drug use illegal, the majority's disposition of this case would not be supportable under well established law governing judicial review of agencies' enforcement discretion. Generally speaking, enforcement priorities are not the business of this Branch, but of the Executive—to whom, and not to the courts, the Constitution confides the responsibility to "take Care that the Laws be faithfully executed," U.S. Const. Art. II, § 3. Preserving that sound allocation of responsibility was one of the purposes, and has been perhaps the primary application, of that provision of the Administrative Procedure Act which excludes from judicial review "agency action ... committed to agency discretion by law." 5 U.S.C. § 701(a)(2) (1976). As this court has accurately stated, "[a]n agency's decision to refrain from an investigation or an enforcement action is generally unreviewable." *Kixmiller* v. *SEC*, 492 F.2d 641, 645 (D.C. Cir. 1974). *See also Action on Safety and Health* v. *FTC*, 498 F.2d 757, 762 (D.C.

Cir. 1974). The reason is well explained in a Supreme Court case that could more easily have been regarded as appropriate for judicial control of agency enforcement policy than the present one, since it involved nonenforcement against some companies combined with enforcement against others:

> [I]n the shaping of its remedies within the framework of regulatory legislation, an agency is called upon to exercise its specialized, experienced judgment. Thus, the decision as to whether or not an order against one firm to cease and desist from engaging in illegal price discrimination should go into effect before others are similarly prohibited depends on a variety of factors peculiarly within the expert understanding of the Commission. . . . [T]he Commission alone is empowered to develop that enforcement policy best calculated to achieve the ends contemplated by Congress and to allocate its available funds and personnel in such a way as to execute its policy efficiently and economically.

Moog Industries v. *FTC*, 335 U.S. 411, 413, 78 S.Ct. 377, 379, 2 L.Ed.2d 370 (1958). *See also Vaca* v. *Sipes*, 386 U.S. 171, 179, 87 S.Ct. 903, 911, 17 L.Ed.2d 842 (1967).

The majority opinion gives its view of enforcement discretion the appearance of reality by quoting from Supreme Court cases that assert a "strong presumption" of reviewability rebuttable only by "clear and convincing" legislative intent to negate review. Maj.Op. at 1183-1184 n.23. These excerpts are misleading, since they are taken from cases or portions of cases that do not involve review of enforcement discretion. Indeed, all but one of them come from cases or portions of cases that do not even deal with the "committed to agency

discretion" provision of the APA (§ 701(a)(2)), but rather with the provision that denies review "to the extent that . . . statutes preclude judicial review" (§ 701(a)(1)). The citation to *Dunlop* v. *Bachowski*, 421 U.S. 560, 567 n.7, 95 S.Ct. 1851, 1858 n.7, 44 L.Ed.2d 377 (1975), is illustrative. The court of appeals in that case, *Bachowski* v. *Brennan*, 502 F.2d 79 (3d Cir. 1974), considered and rejected separate arguments by the Secretary of Labor that (1) the Labor-Management Reporting and Disclosure Act of 1959, 29 U.S.C. § 401 *et seq.* (1976) ("L-MRDA"), *precluded* judicial review of his failure to institute a civil action to set aside a tainted union election, 502 F.2d at 84-86, and (2) his decision not to prosecute was *committed to agency discretion*, *id.* at 86-88. The Supreme Court addressed the first of those arguments in detail, *Dunlop*, *supra*, 421 U.S. at 566-68, 95 S.Ct. at 1857-58. In the context of its preclusion discussion, the Court established that "[i]n the absence of an express [statutory] prohibition," there exists "the strong presumption that Congress did not mean to prohibit all judicial review," *id.* at 567, 95 S.Ct. at 1857. It is this statement upon which the majority here relies. In response, however, to the Secretary's second contention, which is the conention at issue in the present case, the Court

> agree[d] with the Court of Appeals, *for the reasons stated in its opinion*, 502 F.2d 79, 86-88 (CA 3 1974), that there is no merit in the Secretary's contention that his decision is an unreviewable exercise of prosecutorial discretion.

Id. at 567 n.7, 95 S.Ct. at 1858 n.7 (emphasis added). An examination of the cited pages in the appellate court's opinion produces no language even hinting at a

"strong presumption" of reviewability, but rather the contrary implication in its observation that "[n]*ot every* refusal by a Government official to take action to enforce a statute, however, is *unreviewable*," *Bachowski*, *supra*, 502 F.2d at 87 (emphasis added). The court of appeals finds it necessary to carefully distinguish the type of enforcement responsibility given the Secretary under the L-MRDA from the more typical case in which a decision not to enforce is unreviewable. *Bachowski*, *supra*, 502 F.2d at 87-88 & n.11. Thus, *Dunlop* reaffirms the principle of general unreviewability of enforcement decisions.

The other Supreme Court cases cited by the majority also do not support its position. *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967), has even less to do with the present case than the first portion of Dunlop, involving *neither* the "agency discretion" exemption (5 U.S.C. § 701(a)(2)) *nor* agency enforcement action. The Court held that Congress did not intend to "preclude judicial review" (5 U.S.C. § 701(a)(1)) of agency rule-making prior to the enforcement stage. 387 U.S. at 142, 87 S.Ct. at 1512. *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 410, 91 S.Ct. 814, 820, 28 L.Ed.2d 136 (1971), at least involved the relevant provision of the APA; but it did not involve enforcement discretion, and therefore the Court's dictum to the effect that the exception for action "committed to agency discretion" is to be construed narrowly does not establish what the majority suggests. Unless one assumes that the Supreme Court was casually setting forth a rule wildly out of accord with prior case law, the obvious meaning of "narrow construction" was an application that would limit the

exception to enforcement discretion and to a few other matters where either a strong tradition (and therefore congressional expectation) of judicial abstention exists, *see, e.g.*, *Curran* v. *Laird*, 420 F.2d 122 (D.C. Cir. 1969) (en banc), or a specific legislative commitment to discretion is evident, *see Dunlop* v. *Bachowski*, *supra*, 421 U.S. at 595, 95 S.Ct. at 1870 (Rehnquist, J., concurring in the result in part and dissenting in part).[1]

Cases in this circuit no more support narrowing the "agency discretion" exception by an across-the-board application of a "presumption of reviewability" than do the decisions of the Supreme Court.[2] We have sat en banc to consider the subject on two occasions. In the first case, *Curran* v. *Laird*, *supra*, we held that the Executive's decision not to withdraw ships from the national defense reserve fleet fell within the "span of executive actions—pertaining to the fleet's establishment, expansion, curtailment, maintenance and use—that are

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[1] The majority asserts (footnote 25) that the Supreme Court itself has not interpreted *Overton Park* in this fashion, since it cited that case in *Dunlop* to support the proposition that the Secretary of Labor's exercise of enforcement discretion was reviewable. The majority overlooks, however, that both the portion of *Dunlop* in which the citation appears *and* the portion of *Overton Park* to which the citation refers, deal with the possible bar to review posed— *not* by § 701(a)(2), the "committed to agency discretion" provision—but by § 701(a)(1), which relates to statutory preclusion of judicial review. As explained above, I do not dispute that the latter provision requires a clear expression of legislative intent.

[2] The majority's response (footnote 23) fashions a mixture out of this dissent's quite separate assertions regarding Supreme Court case law, on the one hand, and the case law of this and other courts of appeals, on the other hand. I stand by the assertions, unmingled, and must leave it to the reader to dialyze the majority opinion.

'committed to agency discretion' within the meaning of [5 U.S.C. § 701(a)(2)]." 420 F.2d at 128. Our opinion made no mention of a "presumption of reviewability," though the dissent (per Wright, J.) did. *Id.* at 140. Our second en banc consideration of this general subject was *Adams* v. *Richardson*, 480 F.2d 1159 (D.C. Cir. 1973), which not only involved the "agency discretion" exception, but considered its precise application to enforcement discretion. We again did not invoke any "presumption of reviewability" of enforcement decisions, but to the contrary found it necessary to distinguish the prosecutorial discretion cases on the grounds that (1) those cases "do not support a claim to *absolute* discretion," (2) the assertion in the case before the court was not merely deficient enforcement "with regard to a few school districts in the course of a generally effective enforcement program," but rather "conscious[] and express[] [adoption of] a general policy which is in effect an abdication of . . . statutory duty," and (3) the nonenforcement consisted not merely of inaction but of "affirmatively continu[ing] to channel federal funds to defaulting schools." *Id.* at 1162 (emphasis in original). (The centrality of the second point was emphasized in our recent en banc decision of *Adams* v. *Bell*, 711 F.2d 161, 166, 167 & n.35 (D.C. Cir. 1983).)

Nor are the panel opinions of this and other circuit courts cited by the majority any more probative of the novel assertion of a "presumption of reviewability" of enforcement decisions. None of them sets forth such a startling proposition, and all of them display special circumstances overcoming the usual presumption of nonreviewability. Thus, the case requiring an agency to enforce the restrictions of the Davis-Bacon Act (*Carpet,*

Linoleum & Resilient Tile Layers, Local Union No. 419 v. *Brown*, 656 F.2d 564 (10th Cir. 1981)) involved the third factor that we found operative in *Adams* v. *Richardson*, *supra:* the agencies were channeling federal funds to those in violation of the law. The split decision of a panel of this court in *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F.2d 584 (D.C. Cir. 1971), relied upon a statement by the agency making the very finding that triggered mandatory enforcement action under the governing statute; and while reviewing the generalized standard of proof which the agency had established for the exercise of its discretion, the court pointedly declined to review its finding as to whether that standard had been met. 439 F.2d at 595-96. (In the instant case, by contrast, the agency has made a finding that there is *no* "serious danger to the public health or . . . blatant scheme to defraud," Letter from the Commissioner at 3, Jt.App. at 88, and it is this finding which the majority claims power to review.) The panel decisions of this court in *Natural Resources Defense Council, Inc.* v. *SEC*, 606 F.2d 1031 (D.C.Cir. 1979), and *WWHT, Inc.* v. *FCC*, 656 F.2d 807 (D.C. Cir. 1981), are not apposite, since they involved refusal to conduct rulemaking, rather than enforcement discretion in the sense of a refusal to proceed against alleged law violators. And even in that context, the dicta of these cases do not support a presumption of reviewability in the sense here at issue. *Natural Resources Defense Council* states that the *totality* of § 701(a) (which reads "This chapter applies, according to the provisions thereof, except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law") creates a

"strong presumption of reviewability," 606 F.2d at 1043. Undoubtedly so. But that does not suggest that the presumption applicable to the totality of agency action is applicable to the narrow category of action consisting of refusal to adopt rules. To the contrary, the opinion makes it clear that with respect to that category "the relevant factors incline against reviewability," *id.* at 1047. As for *WWHT*, its dicta (which again are applicable only to the weaker case of refusal to adopt rules) are based upon a terminology which resolves the problems at issue here under the rubric of "scope of review" rather than "reviewability."[3]

The short of the matter is that, far from there being a "presumption of reviewability" with regard to enforcement determinations, the well known presumption is precisely the contrary. As the author of the majority opinion noted in dissenting from our en banc decision in *Curran* v. *Laird*, *supra*:

> This "presumption of reviewability" is often regarded as reversed for certain types of Executive actions. Actions relating to the conduct of foreign or military affairs have not formally been reviewed

[3] When particular agency action can be set aside by the courts only for a narrow category of alleged infractions (*e.g.*, complete abdication of enforcement responsibility, *See Adams* v. *Richardson*, *supra*) it is possible to describe that situation by saying *either* that the agency action is not generally reviewable *or* that it is reviewable but "the scope of review [is] very narrow," *WWHT, Inc.* v. *FCC*, *supra*, 656 F.2d at 809. In this opinion I have used the former formulation—not only because I prefer it but because that is what the majority has used, as is evident from the fact that all of the issues here discussed are addressed in that portion of its opinion entitled "Judicial Review of Enforcement Discretion," Maj.Op. at 1183, rather than the portion entitled "Scope of Judicial Review," Maj.Op. at 1188.

> by the courts, absent exceptional circumstances.... Thus we would not normally review the failure of the Executive to exercise emergency powers granted it for the purpose of meeting the military needs of the nation.

420 F.2d at 141 (Wright, J., dissenting). Enforcement decisions are unquestionably one of those "certain types of Executive action" to which this analysis properly applies. Even those who favor general review of decisions not to undertake enforcement action acknowledge that it will constitute a change in the law, since "reluctance to review remains entrenched." Note, *Judicial Review of Administrative Inaction*, 83 COL.L.REV. 627, 658 (1983). The majority seeks to dismiss established law by citing Professor Davis for the proposition that "the real 'key lies in recognizing that the law has been in transition and that the case law * * [is now] strongly on the side of reviewability.'" Maj.Op. at 1187-1188, *quoting from* 2 K. DAVIS, ADMINISTRATIVE LAW TREATIES § 9.6 at 239-40 (2d ed. 1979). This also is misleading. The quoted statement was made in the context of a discussion dealing largely with the enforcement discretion of criminal prosecutors, which had previously been asserted to be not merely (as the cases establish with regard to the enforcement discretion of administrative agencies) *generally* unreviewable, but *entirely* so. As a refutation of that bald proposition, whether applied to criminal or administrative enforcement, Davis's statement is entirely accurate. But neither the statement, nor the cases upon which it relies, support any general presumption of reviewability in the sense at issue here.

Proceeding, then, from the premise that an agency's exercise or (*a fortiori*) nonexercise[4] of its enforcement discretion is generally unreviewable, one must consider whether there are any special circumstances justifying departure from that general rule in the present case. I am aware of none, and the majority opinion has assuredly not suggested any. Its reliance (footnote 29) upon the mandatory terms of the statute ("any person who violates § 331 'shall' be imprisoned or fined," citing 21 U.S.C. § 333(a) (1976)) is half-hearted, and properly so. Most of the criminal code is cast in such mandatory terms, and yet prosecutors' discretion not to indict is the archetype of unreviewable enforcement discretion. Besides which it is the Justice Department, rather than the FDA, that executes § 333(a). *See* 21 U.S.C. § 335.

The opinion places its major reliance upon what it calls the FDA's "Policy Statement," the relevant portion of which is set forth at page 1186. Even if an agency's failure to follow its rules regarding enforcement policy is reviewable (which may not be the case, *see, e.g., United States* v. *Snell*, 592 F.2d 1083 (9th Cir.1979)); and even if the statement in question constituted an agency rule (which it did not, as will be discussed below); it is impossible to see how that "rule" has been violated here. The statement is full of flexible terms, the precise application of which was obviously intended to be, and could properly be, left to the discre-

[4] It is interesting to note that Professor Davis's statement discussed in text applied only to decisions to prosecute. Even in the limited sense in which that statement is to be understood (availability of review in *some* instances) it is not extended to "prosecutors' decisions not to prosecute," as to which "the law is still somewhat unclear." 2 K. Davis *supra*, § 9.6 at 244.

tion of the agency—for example, whether an unapproved use has become "widespread"; whether it "endangers the public health"; what particular action "is warranted to protect the public"; the meaning of the phrase "when necessary." *Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed.Reg. 16503, 16504 (1972). Moreover, the last paragraph of the quoted excerpt, which is apparently intended to give more precise content to the first paragraph, suggests that the intended actions, as discretionary as they are, are only to be taken where "any person in the chain of distribution ... does anything that directly or indirectly suggests to the physician or to the patient that an approved drug may properly be used for unapproved uses." *Id.* It applies, in other words, where misbranding has occurred—which (as will be discussed in the next part) is not the case here.

More fundamentally, however, the quoted statement is not an agency rule, and is indeed not even an authoritative policy statement. The majority's opinion gives it the title "Policy Statement" (which it never bore), *see* Maj.Op. at 1176 & n.3, and uses that conclusory designation throughout. In fact, however, the statement was part of the policy justification set forth in a Notice of Proposed Rulemaking, with respect to a proposal that was never adopted. The paragraphs quoted by the majority, *id.* at 1186, and particularly the first of them, recite principles that are more specifically embodied in the subsequently recited text of the proposed amendment to 21 C.F.R., *see* 37 Fed.Reg. at 16504. It is remarkable to suggest that, although the text of the rule was rejected, the substance of that text was authoritatively adopted by the mere recital of it in the notice of

Proposed Rulemaking. Even if one is to accept (as I am not inclined to) the expansive dictum in two of our cases referred to by the majority that the term "rule" is "broad enough "to include nearly every statement an agency may make," *Center for Auto Safety* v. *NHTSA*, 710 F.2d 842, 846 (D.C. Cir. 1983), *quoting Batterton* v. *Marshall*, 648 F.2d 694, 700 (D.C. Cir. 1980), surely the exceptions must at least include statements of principles that the agency is *thinking* of adopting but ultimately decides *not* to adopt. It is the height of irrationality to equate the prologue of a rejected rule with (what was involved in *Center for Auto Safety*) an agency's authoritative statement of its reason for withdrawing a notice of proposed rule. As *Center for Auto Safety* observed, *quoting from Columbia Broadcasting Systems, Inc.* v. *United States*, 316 U.S. 407, 416, 62 S.Ct. 1194, 1199, 86 L.Ed. 1563 (1942):

> [I]t is the substance of what the [agency] has purported to do and has done which is decisive.

710 F.2d at 846. Here, what the agency purported to do and did by its proposal and nonadoption was *nothing*—unless it was to *disapprove* the principles which the proposal and its prologue contain.

The opinion seeks to remedy this patent deficiency by observing that the "FDA still considers [the so-called Policy Statement] binding and to have substantive effect," Maj.Op. at 1186. That is not so. The majority's citation to support that conclusion is to a portion of the agency's Memorandum in Support of the Defendant's Motion to Dismiss, which (in turn referring to the Commissioner's letter response to the Appellants' request) only concedes that the Notice sets forth the agency's position on "the legal status of approved labeling for prescription drugs." Jt.App. at 131 n.10. That legal status has *nothing to do* with the rigid and detailed enforcement obligations which the opinion suggests the agency has imposed upon itself.

Thus, there is ultimately no special factor to support the extraordinary assertion of authority to control the agency's enforcement discretion in the present case—nothing, except the majority's disagreement with the agency's determination that no serious danger to the public health exists. But we are not the only public officials endowed with intelligence and worthy of trust, and our system of laws has committed the relative evaluation of public health concerns to others. Moreover, even if the clear erroneousness of an agency's reason for not conducting enforcement activities were a proper basis for our intervention (which it is not), there is no clear error here. Without belittling the humane concerns associated with the present complaint, it must be acknowledged that the public health interest at issue is not widespread death or permanent disability, but (at most) a risk of temporary pain to a relatively small number of individuals (200, which the majority swells to 1,100 by including prisoners under sentence of death in states that have *not* adopted lethal injection statutes). Moreover, it is not a matter of pain versus no pain, but rather pain of one sort substituted for pain of another—*and in all likelihood substitution of a lesser pain, since that is the principal purpose of the lethal injection statutes.*[5] In these circumstances, it is hardly

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[5] *See* Gimlin, *Administering the Death Penalty*, Editorial Research Rep., Weekly Reminder Service, August 19, 1977:

> The public hanging, with its circus atmosphere, disappeared in America early in this century. But then the electric chair, installed as a more humane device for snuffing out life, has produced a host of grim stories from witnesses

clear error to determine that lethal injection statutes do not pose a "serious danger to the public health," justifying the diversion of FDA enforcement resources from other projects. Indeed, it seems to me the conclusion that they do pose a serious danger is fanciful.[6]

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at the death scene. The gas chamber, usually regarded by penal officials as an improvement over the electric chair, requires a sealed room and a strapped-in victim....

Oklahoma and Texas have since moved in a new direction, providing for execution by lethal injection. "I think and I hope this will provide some dignity with death," Texas Gov. Dolph Briscoe said last May when he signed the injection bill into law, ... Briscoe could have added that for years veterinarians have considered the lethal injection the most "humane" way of putting hopelessly crippled or diseased animals out of their misery.

The Report cited repeatedly the the majority, ROYAL COMMISSION ON CAPITAL PUNISHMENT, 1949-1953 REPORT (1953), said that "intravenous injection, if practicable, would fulfill our three requisites [of humanity, certainty and decency] better than any other method." *Id.* at 257. The Report doubted, however, the methods' practicability, on the basis of medical knowledge and technique thirty years ago, and therefore rejected it for the time being, but recommended "unanimously and emphatically, that the question should be periodically examined, especially in the light of progress made in the science of anaesthetics, with a view to a change of system being proposed to Parliament as soon as it can be shown that there are no longer any grounds for the doubts that now deter us from recommending it." *Id.* at 261. The Report's verdict concerning the alternative means of execution that these 200 prisoners will undergo if lethal drugs are not used is a good deal less qualified: "[W]e cannot recommend that either electrocution or the gas-chamber should replace hanging as the method of judicial execution in this country. In the attributes we have called 'humanity' and 'certainty' the advantage lies, on balance, wit hanging." *Id.* at 256.

[6] The majority opinion seeks to preclude consideration of the realities of the matter by asserting that the Commisioner "irrebuttably presume[d] that 'duly authorized statutory enactments * * * [which further] proper State functions' cannot, as a matter of law, pose such a danger to the public." Maj.Op. at 1190. That is not so. What the Commissioner wrote was that

As for the "anachronistic ring" which the majority hears in all this (Maj.Op. at 1188 n.36): If the clear statements of this court, *see Kixmiller* and *Action on Safety and Health*, *supra*, become downright anachronisms in nine years, we should perhaps stop publishing our opinions. I fancy, however, that the sound which the majority heard was not an anachronistic ring at all, but the stifled cry of smothered stare decisis, or per-

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"[w]e cannot conclude that those dangers [of a serious risk to the public health or a blatant scheme to defraud] are present under State *lethal injection* laws, *which* are duly authorized statutory enactments in furtherance of proper State functions. Letter to the Commissioner at 3, Jt.App. at 88 (emphasis added). If, in that excerpt, the phrase "lethal injection" were omitted, or the word "which" were replaced with the words "since they," it would be possible to assert that the Commissioner was maintaining that no serious health hazard was presented *only* by virtue of the fact that these were state laws. As written, however, the excerpt refers to the specific nature of these laws ("lethal injection laws")—and therefore does not exclude from the Commissioner's calculus the factors discussed in text. The descriptive phrase, "which are duly authorized, etc.," reflects an important element in the Commissioner's analysis, but not necessarily the only dispositive one. To interpet the statement as an assertion that whatever is provided by state law will not be challenged by the FDA would render it quite incompatible with the Commissioner's statement in the preceding paragraph that "[w]e do not say, of course, that provisions of State law that are contrary to the Federal Food, Drug, and Cosmetic Act are lawful." *Id.*

There is no authority for the majority's assertion that the Commissioner's statement of "no serious danger to the public health" is not enough, but that he must "give rational reasons" why that is so. Maj.Op. at 1190 n.43. Indeed, I know of no authority for the proposition that an agency must provide any ground for its refusal to comply with a request for exercise of its enforcement discretion, much less that it must provide the analysis underlying that ground. This seems to me one of those novel procedural requirements we have been told not to invent. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 98 S.Ct. 1197, 55 L.Ed.2d 460 (1978).

haps the far-off shattering of well established barriers separating the proper business of the executive and judicial branches.

II. JURISDICTION

If, however, the discretion issue is found against the FDA, it becomes necessary to establish the existence of FDA authority to take the requested action. The majority opinion fails to carry this point as well. It properly demolishes the agency's reliance upon state action, *see* Maj.Op. at 1179-1181, but does not address the more serious obstacle: FDA jurisdiction depends upon the existence of misbranding under § 331(k), which cannot be established under the facts of this case.

The majority opinion concludes and summarizes its discussion on the jurisdictional point as follows:

> the states' lethal injection statutes purport to mandate the use of certain prescription drugs for a purpose not listed on their label.... FDA *therefore* must have jurisdiction to regulate such activity.

Maj.Op. at 1182 (emphasis added). This progression of thought does not follow unless the opinion establishes the intermediate proposition that "using prescription drugs for a purpose not listed on their label is unlawful under the FDCA." It makes no attempt to establish that proposition—principally I think, because it is impossible to do so. The FDCA is directed at the sale and distribution of drugs rather than their use. The only provision that could remotely apply here is the prohibition against "the doing of any ... act with respect to ... a ... drug ... [which] results in such article being ... misbranded," 21 U.S.C. § 331(k). Even if one adopts the extraordinary notion that a person causes an article

to be misbranded by simply using it for a purpose not stated on the label, § 331(k) would still not apply, since—in accordance with the Act's focus upon sale and distribution rather than drug use—it requires that the misbranding occur "while such article is held for sale (whether or not the first sale) after shipment in interstate commerce." *Id.* Here the drugs are in the possession of the states' penal authorities. Under no conceivable interpretation of the English language could they be deemed "held for sale."

The majority opinion points out, quite correctly, that § 331(k) was added to the Act with the intent of expanding its application. Given the fact that the Act's primary application was to commercial transactions, it *was* a vast expansion to extend it to sales within a state after the first sale following shipment in interstate commerce. Nonetheless, that expansion was still limited to misbranding which occurs "while such article is held for sale." This is a statute that bears criminal penalties, and it is simply not possible to disregard this qualification entirely, as the majority would do. It is sometimes improper to "look only to the statutory language," Maj.Op. at 1181; but it is always improper—and opens the gates much more widely to judicial abuse—to ignore intentional statutory language entirely. Thus, I would acknowledge that the expansive intent of the amendment may be invoked to extend the statutory text to all "holding" that occurs while the drug is in the stream of commerce from manufacturer to ultimate consumer, *see United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92, 84 S.Ct. 559, 563, 11 L.Ed.2d 536 (1964). But not beyond that point. Given the statutory language "held for sale," it is clear that when the House

Report, quoted by the majority (p. 1181), said that the intent of the 1938 amendment was to "extend the protection of consumers contemplated by the law to the full extent constitutionally permissible," it was using the word "consumer" in the sense of "purchaser" rather than "ingester"—just as "consumer protection" refers to shoppers rather than gourmets, and the consumer price index to purchasers rather than eaters. Thus, in the context of discussion of this statute, the majority's notion of an "unwilling consumer," Maj.Op. at 1182, does not compute.

None of the cases relied upon by the majority to support the principle of expansive interpretation involves an expansiveness beyond the field of actual sale. *United States* v. *Sene X Eleemosynary Corp.*, 479 F.Supp. 970 (S.D.Fla.1979), involved the issue of whether the drug was "held for sale" when it was compounded with another substance for sale; *United States* v. *10 Cartons Labeled, in Part, "Hoxsey"*, 152 F.Supp. 360 (W.D.Pa.1957), held (erroneously, as later case law has established) that a physician can misbrand a drug by using it, as part of a paid-for therapy, for an unapproved use. Even those sharing the majority's apparent disdain for the plain meaning of statutory language would be hard pressed to explain why, to express the concept of *any* transmission to the ultimate ingester (as opposed to the ultimate purchaser) of the drug, Congress should choose the peculiarly inapt phrase "held for sale." And the consequences that ensue are as implausible as the interpretation that produces them: It cannot seriously be thought that the householder who administers a drug to his child for an unapproved use, or who places it in an unmarked bottle on his medicine

shelf to administer later for an *approved* use, violates the criminal provisions of the Food, Drug, and Cosmetic Act. In short, even giving the phrase "held for sale" the minimum content it can possibly contain without reading it out of the statute entirely, it does not cover the holding by a state for purposes of coerced administration of the drug to execute a sentence of capital punishment. In that context, the state is as much the ultimate consumer of the drug as it was of the electricity previously used for the same purpose; and the condemned prisoner executed by injection is no more the "consumer" of the drug than is the prisoner executed by firing squad a consumer of the bullets. Thus, misbranding has not occurred in the present case.

The majority opinion attempts, once again unsuccessfully, to condemn the agency out of its own mouth. The majority asserts that "[i]n both [prison clinical investigations and veterinary practices] FDA has rejected arguments that it does not have authority to regulate unapproved uses of approved drugs." Maj.Op. at 1180. But examination of the citations shows that in the first of these situations the commission was proceeding not under the more general portions of the statute at issue here, but under its specific authority to regulate clinical testing of drugs, *see* 21 U.S.C. §§ 355(i), 357(d); 21 C.F.R. § 50.44 (1982); and that the second situation involved assertion not of authority to regulate use, but of authority to require proper labeling of drugs sold for a particular use. *See United States* v. *Beuthanasia-D. Regular*, [1979 Transfer Binder] Food Drug Cosm.L.Rep. (CCH)¶ 38265 (D.Neb.1979). Of course even if the FDA had acknowledged what the opinion suggests, we are not in the habit of permitting an

agency to expand its authority by simply acknowledging the legitimacy of such expansion. Except for special provisions such as that alluded to above pertaining to clinical or investigative drug use, there is nothing in the statute giving the Commission "authority to regulate unapproved use of approved drugs."

* * *

The majority discerns that "the FDA is clearly refusing to exercise enforcement discretion because it does not wish to become embroiled in an issue so morally and constitutionally troubling as the death penalty." Maj.Op. at 1192. I doubt that. As discussed above, there were plenty of well supported reasons for the Commission to refuse to act. If speculations as to motivation are to be indulged in, I would suggest that the agency was properly refusing to permit its powers and the laws it is charged with enforcing from being wrongfully enlisted in a cause that has less to do with assuring safe and effective drugs than with preventing the states' constitutionally permissible imposition of capital punishment. This court should have done the same. It is our embroilment, rather than the FDA's abstention, that is remarkable.

I would affirm on the basis of the opinion below.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 82-2321

LARRY LEON CHANEY, ET AL., APPELLANTS

v.

MARGARET HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES

Appeal from the United States District Court
for the District of Columbia
(Civil Action No. 81-02265)

On Suggestion for Rehearing *En Banc*

[Filed January 17, 1984]

Before: ROBINSON, *Chief Judge*; WRIGHT, TAMM, WILKEY, WALD, MIKVA, EDWARDS, GINSBURG, BORK, SCALIA and STARR, *Circuit Judges*.

ORDER

Appellee's suggestion for rehearing *en banc* has been circulated to the full Court. A majority of the Judges in

regular active service have not voted in favor of the suggestion. On consideration of the foregoing, it is

ORDERED by the Court *en banc* that Appellee's suggestion is denied.

Per Curiam

Circuit Judges Wilkey, Ginsburg, Bork, Scalia and Starr would grant the suggestion for rehearing *en banc*. A statement by Circuit Judge Scalia, joined by Circuit Judges Wilkey, Bork and Starr, is attached.

Circuit Judge Edwards abstains.

Statement on the denial of rehearing *en banc*, filed by *Circuit Judge* SCALIA, in which *Circuit Judges* WILKEY, BORK and STARR concur.

SCALIA, *Circuit Judge*: For the reasons stated in my dissent from the panel opinion, I believe that opinion to be in error, both with regard to the scope of the Food and Drug Administration's jurisdiction, and with regard to the issue whether the decision that the court took upon itself was "committed to agency discretion by law" within the meaning of the Administrative Procedure Act, 5 U.S.C. § 701(a)(2) (1982). Both issues seem to me of sufficient significance and of sufficiently general application to warrant the attention of the full court. Especially the latter, however, which bears upon the enforcement authority of all federal agencies.

The panel's determination that there exists a "general presumption of reviewability" of enforcement decisions distorts the law and usurps the authority of the Executive Branch. It is particularly worth the attention of the full court because it rests upon a novel interpretation of Supreme Court precedent that has now appeared in several of our panel opinions. The Supreme

Court has said that action is to be deemed "committed to agency discretion by law" when the governing statute is "drawn in such broad terms that in a given case there is no law to apply." *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 410 (1971), *quoting from* S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945). The panel opinion renders this guidance quite literally meaningless by asserting that "whether there is law to apply turns on such pragmatic considerations as whether judicial supervision is necessary to safeguard plaintiffs' interests, whether judicial review will unnecessarily impede the agency in effectively carrying out its congressionally assigned role, and whether the issues are appropriate for judicial review." Slip op. at 22, *citing Natural Resources Defense Council, Inc.* v. *SEC*, 606 F.2d 1031, 1043-44 (D.C. Cir 1969). The same test has been applied by this Circuit to sustain review in *Falkowski* v. *EEOC*, 719 F.2d 470, 480, n.16 (D.C. Cir. 1983); *Local 1219, American Federation of Government Employees* v. *Donovan*, 683 F.2d 511, 515 (D.C. Cir. 1982); and *WWHT, Inc.* v. *FCC*, 656 F.2d 807, 816 (D.C. Cir. 1981); and has been purportedly followed by other Circuits (though in denying review) in *Tuepker* v. *FHA*, 708 F.2d 1329, 1332 (8th Cir. 1983); and *Sinai Hospital* v. *Horvitz*, 621 F.2d 1267, 1270 (4th Cir. 1980). This seems to me not an application of the Supreme Court's guidance, but the substitution of an entirely different test—which can be summarized by saying that we intervene when we think it a good idea. The recited "pragmatic considerations" bear no rational relationship to "whether there is law to apply." One could with equivalent logic recite them as the definition

of "injury in fact"—or of almost any other concept that needs evisceration.

Because of the importance of this issue in particular, I note my dissent from the denial of rehearing en banc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 81-2265

LARRY LEON CHANEY, ET AL., PLAINTIFFS,

v.

RICHARD S. SCHWEIKER, SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
DEFENDANT.

[Filed Aug. 30, 1982]

MEMORANDUM OPINION

This case presents the question of whether the Secretary of the Department of Health and Human Services and his designated agent, the Commissioner of Food and Drugs, abused their discretion by declining to exercise their regulatory authority under the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. § 301 *et seq.* (1976 & Supp. IV 1980) (hereinafter "FDC Act" or "the Act") to prevent the states of Oklahoma, Texas, Idaho, and New Mexico from utilizing certain prescription drugs for the purpose of administering the death penalty through the medium of lethal injections. Plaintiffs are inmates at the Oklahoma State Penitentiary and the Ellis Unit of the Texas Department of Corrections and are under sentence of death by lethal injection. The gravamen of their complaint for declaratory and injunctive relief is that the Secretary and the Commissioner have ignored their statutory obligations by refusing to take specific remedial steps ostensibly de-

signed to insure that drugs administered in state-mandated lethal injection procedures are demonstrated to be safe and effective for that particular purpose. *See* 21 U.S.C. § 355. In addition, plaintiffs maintain that since all of the formal requisites for the assertion of jurisdiction by the Food and Drug Administration (hereinafter "FDA") allegedly have been satisfied here, the Commissioner is therefore *required* to exercise his extensive regulatory power over drugs utilized by the states to execute condemned prisoners. For the reasons stated herein, the Court has concluded that the Commissioner's decision to refrain from interfering with the implementation of state capital punishment statutes constitutes a defensible exercise of his considerable investigative and enforcement discretion under the FDC Act. There are no issues of material fact remaining in dispute, and the defendant, accordingly, is entitled to judgment as a matter of law.

BACKGROUND

In recent years, the states of Oklahoma, Texas, Idaho, and New Mexico have adopted capital punishment statutes mandating the use of marketable prescription drugs for administering the death penalty by lethal injection. These statutes generally provide that prisoners sentenced to death for capital offenses shall be executed by intravenous administration of a short-acting barbiturate in combination with a chemical paralytic agent.[1] Although neither the statutes nor the ap-

[1] The Oklahoma statute is representative of these lethal injection laws in its description of the method of execution to be followed by the state:

> The punishment of death must be inflicted by continuous, intravenous administration of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician according to accepted standards of medical practice.

Okla. Stat.Ann. tit. XXII, § 1014A (West Supp. 1981-1982).

plicable implementing regulations adopted in Idaho and New Mexico identify the drugs to be utilized by prison officials in administering the death penalty, the drugs specified in the relevant Oklahoma and Texas regulations are quite clearly manufactured for distribution and sale in interstate commerce. *See* 21 U.S.C. § 321(b).[2] Each of these drugs may be lawfully manufactured and marketed for various medical and therapeutic uses,[3] but none has been approved by the FDA for the non-therapeutic purpose of executions.

On December 19, 1980, plaintiffs filed a citizen petition with the Secretary of Health and Human Services (hereinafter "the Secretary") pursuant to 21 C.F.R.

[2] According to the Oklahoma Department of Corrections Policy and Procedures Memorandum No. OP-050301 (Revised), issued July 21, 1981, and the Texas Department of Corrections Procedures for the Execution of Inmates Sentenced to Death, the ultrashort-acting barbiturate to be used in all executions is sodium thiopental. The Oklahoma Memorandum also states that the chemical paralytic agent to be administered in all lethal injections is either tubocrarine, succinylcholine chloride, or potassium chloride.

Sodium thiopental is manufactured by Abbott Laboratories of North Chicago, Illinois. Tubocurarine is manufactured by Eli Lilly and Company of Indianapolis, Indiana. Succinylcholine chloride is manufactured by Squibb & Sons, Inc. of Princeton, New Jersey, and Burroughs Wellcome Co. of Research Triangle Park, North Carolina. Potassium chloride is manufactured by Invenex Laboratories of Orlando, Florida. *See Phsicians Desk Reference* (35th ed. 1981).

[3] Sodium thiopental is an anesthetic and hypnotic drug commonly utilized in medical and surgical procedures to induce sleep. Tubocurarine and succinylcholine chloride are effective muscle relaxants generally utilized as adjuncts to anesthesia. Potassium chloride is widely used as a potassium supplement.

§ 10.30 (1980), requesting that the FDA undertake specific investigatory and enforcement action to prevent the unapproved potential use of marketed prescription drugs as lethal injections to execute condemned prisoners.[4] In their petition, plaintiffs asserted that the untested and unapproved use of prescription drugs to execute state prisoners violates the provisions of section 505(a) of the FDC Act, 21 U.S.C. § 355(a), which generally prohibits the interstate distribution of any "new drug"[5] unless the Secretary has approved an application supported by substantial evidence[6] which demon-

[4] *See* Exhibit A To Plaintiffs' Memorandum In Support Of Their Motion For Summary Judgment And In Opposition To Defendant's Motion To Dismiss Or, In The Alternative, For Summary Judgment (hereinafter "Plaintiffs' Memorandum").

[5] The term "drug" is defined in section 201(g)(1) of the Act, 21 U.S.C. § 321(g)(1), to include

> ...(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

[6] The term "substantial evidence" is defined in section 505(d) of the Act, 21 U.S.C. § 355(d), to mean

> ...evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

strates the drug's safety and effectiveness. By its express terms, section 505 requires premarketing approval for "any new drug" unless it is exempt under the grandfather provisions of the Act or intended solely for investigative use. *See 21 U.S.C.* §§ 321(p)(1), 355(i). Moreover, section 201(p)(1) of the Act defines the term "new drug" (which includes the majority of prescription drugs) to encompass "[a]ny drug ... not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof...."[7] Plaintiffs supplemented their petition with documentary evidence designed to support their position that the *only* available evidence concerning the safety and effectiveness of the aforementioned drugs for use in administering the death penalty strongly indicates that the lethal injection procedure is not a swift, painless, and humane medium for inducing the cessation of bodily functions. On the basis of the affidavits[8] and other supporting documentation appended

[7] The Supreme Court has stated that general recognition of a drug's safety and effectiveness for intended uses requires an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in section 505(d) of the Act, 21 U.S.C. § 355(d). *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-634 (1973).

[8] The affidavits submitted by licensed physicians in conjunction with plaintiffs' petition indicate that there is currently no "expert consensus" derived from "adequate and well-controlled investigations" that the drugs to be administered to condemned inmates will produce loss of consciousness and death without delay or discomfort. Moreover, these physicians aver that there are no published scientific data which even address the use of these drugs as a means of executing human beings. Finally, the physicians maintain that participation by any doctor in the or-

to their petition, plaintiffs requested the Secretary to prevent these states from utilizing prescription drugs in state-mandated executions until scientifically valid tests conducted by the sponsors of those drugs firmly established their safety and effectiveness for the contemplated use.

Plaintiffs also maintained in their petition that the drugs that have been designated for use in lethal injection procedures are "misbranded" under the Act because they do not contain "adequate directions *for* use" in administering the death penalty, as ostensibly required by section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), or adequate warnings that this contemplated use may be dangerous and inhumane. The FDA has interpreted this statutory provision to require that all drugs distributed through the channels of interstate commerce contain "directions under which *layman* can use a-drug safely and for the purpose for which it is intended";[9] the effect of that implementing regulation is

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dering, preparation, or administration of prescription drugs as a means of implementing the death penalty is flatly prohibited by the Hippocratic Oath, which has served as the ethical foundation of the medical profession for 2500 years. The American Medical Association and the professional medical societies of each of the four states that have adopted lethal injection statutes have endorsed or promulgated resolutions which declare that a physician, as a member of a profession dedicated to the preservation of human life, should not participate in any way in an authorized execution unless such "participation" is limited to making a determination or certification of death. See Affidavits of Dr. Ward Casscells, Dr. Richard S. Hodes, and Dr. Leroy David Vandam, Exhibit A To Plaintiffs' Memorandum.

[9] 21 C.F.R. § 201.5 (1982) (emphasis supplied). The "intended use" of a drug refers to "the objective intent of the persons legally responsible for the labeling of drugs," such as manufacturers, wholesalers, or retailers. 21 C.F.R. § 201.128.

to make it impossible for any *prescription* drug to comply with the statutory directive unless it qualifies for an exemption, because prescription drugs by definition can be used only under the supervision of a licensed physician. *See* 21 U.S.C. § 353(b)(1).

Pursuant to 21 C.F.R. § 201.100 (1982), the FDA has exempted prescription drugs from the restrictions imposed by section 502(f)1 of the Act, as long as availability of each drug is conditioned upon a) a prescription from a licensed medical practitioner, and b) a label bearing appropriate cautionary language and a detailed description for pharmacists and physicians designed to insure that the drug is properly prescribed, dispensed, and administered. In addition, the FDA requires that any "new drug" subject to section 505 of the Act bear a label that has been authorized by the FDA through an approved new drug application (NDA). *Id.* Plaintiffs have pressed the argument that the absence of FDA approval of a NDA which would permit the marketing of the prescription drugs at issue here for use in state-mandated lethal injections renders the prescription drug exception set forth in 21 C.F.R. § 201.100 inapplicable and compels the conclusion that those drugs are "misbranded" under the Act.[10] In other words, plaintiffs submit that because state prison systems which have obtained the drugs at issue through the channels of interstate commerce intend to use the drugs for the purpose of executing human beings, FDA regulations require those prisons to provide "adequate directions

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[10] Misbranded drugs, no less than unapproved new drugs, may not be lawfully introduced into interstate commerce. *See* 21 U.S.C. § 331(a).

for use" within the meaning of 21 C.F.R. § 201.5.[11] Finally, plaintiffs asserted that these allegedly misbranded drugs are "held for sale [by the states] after shipment in interstate commerce," and are thus fully subject to the prohibitory language of 21 U.S.C. § 331(k).[12]

At the conclusion of their petition, plaintiffs requested the Secretary to take the following specific enforcement steps to prevent the states from using prescription drugs in administering the death penalty:

1) Affix a boxed warning to the labels of the drugs designated by statute or prison policy for use in state-supervised lethal injection procedures, declaring that those drugs are not approved for use as a means of execution, are not considered safe and effective for that use, and should not be so employed by any state;

2) Notify the manufacturers of the drugs and appropriate prison officials in Oklahoma, Texas, Idaho, and New Mexico that the drugs designated by statute or prison policy for use in administering the death penalty by lethal injection are not approved for use as a means of execution, are not considered safe and effective for that use, and should not be so employed by those states;

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[11] Plaintiffs do not and indeed cannot suggest that these prescription drugs were developed and marketed by their *manufacturers* for the purpose of executing condemned prisoners. To reiterate, each of these drugs has been formally approved by the FDA and/or lawfully marketed and labeled for specific medical and therapeutic uses.

[12] That subsection prohibits "the doing of any . . . act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated or misbranded."

3) Place in the *Drug Bulletin* an article advising that the drugs specified for use in state-supervised lethal injection procedures are not approved for use as a means of execution, are not considered safe and effective for that use, and should not be so employed;

4) Adopt and implement a policy for the seizure and condemnation from state prisons or departments of corrections of drugs which are destined or held for use as a means of execution;

5) Recommend the prosecution of manufacturers, wholesalers, retailers and pharmacists who knowingly sell drugs for the unapproved use of administering lethal injections, and of prison officials who knowingly buy, possess, or use drugs for that unapproved purpose. Plaintiffs' Memorandum, at 6-7 n.4. Finally, plaintiffs requested the Secretary to provide them with a hearing on any controlling issue of fact raised by their petition.

On July 7, 1981, the Commissioner of Food and Drugs denied plaintiffs' petition without addressing the merits of plaintiffs' "new drug" and "misbranding" theories of statutory violations. In his response to the petition, the Commissioner noted general agreement with plaintiffs' position that the FDA has the authority and responsibility to prevent the promotion and use of certain drug products for purposes not included in the labeling of those drugs. Nevertheless, the Commissioner's review of the statute, the implementing regulations, and applicable precedent ultimately led him to conclude that the FDA's jurisdictional authority did not extend to the state-sanctioned use of prescription drugs in administering the death penalty by lethal, injection. Alternatively, the Commissioner concluded that even if the FDA did have jurisdiction as a statutory matter to

grant plaintiffs the extensive relief that they had requested, he would nonetheless decline as a matter of inherent enforcement discretion to pursue wide-ranging investigative and enforcement action which would effectively preclude four states from implementing duly authorized capital punishment statutes enacted in furtherance of proper state functions.

Plaintiffs thereupon filed the instant action pursuant to 28 U.S.C. §§ 1331, 1361 (1976 & Supp. IV 1980), seeking declaratory, injunctive, and mandamus relief to compel the Secretary and his agent, the Commissioner of Food and Drugs, to immediately hold evidentiary hearings designed to ascertain whether the lethal injection procedure authorized by the states of Oklahoma, Texas, Idaho, and New Mexico conforms to the requirements of the FDC Act. In addition, plaintiffs seek an order requiring the Secretary and the Commissioner to carefully consider whether any of the enforcement steps originally requested by plaintiffs in their petition may be necessary to remedy alleged violations of the Act.

DISCUSSION

At the outset, it is important to recognize what is *not* at issue in this lawsuit. First and foremost, this case does not present constitutional issues concerning the appropriateness of either the death penalty in general or the lethal injection procedure in particular. Second, the Court has not been asked to evaluate the ultimate merits of the "new drug" and "misbranding" theories that plaintiffs have advanced as a legal justification for regulatory action by the FDA. The sole issue for decision is whether the Secretary and the Commissioner have a ministerial duty under the FDC Act to exercise

their considerable investigatory and enforcement powers to insure that prescription drugs utilized by prison officials to administer a lethal injection death penalty are safe and effective for that purpose. In confronting that issue, the Court declines to review the Commissioner's determination that the FDA lacked jurisdiction to interfere with the state-sanctioned use of marketed prescription drugs in lethal injection procedures. Instead, the Court simply holds that the putative availability of a jurisdictional foothold for providing plaintiffs with the relief that they requested does not impose upon the Commissioner a mandatory duty to institute desired regulatory action. Accordingly, the Court will uphold the Commissioner's legitimate exercise of enforcement discretion without reviewing the bona fides of his interpetation of the Act's jurisdictional span.

The principal difficulty with plaintiffs' position in this litigation stems from their apparent assumption that the absence of any express or implied exemption in the FDC Act for the state-sanctioned procedure of administering death by lethal injection somehow *compels* the Commissioner to assert jurisdiction over this particular unapproved use of prescription drugs. Having constructed a somewhat attenuated analytical framework to justify subjecting lethal injections to the strictures of the Act's "new drug" and "misbranding" provisions, plaintiffs now maintain that the Commissioner has *no* discretion to decline to initiate requested investigative and enforcement proceedings when confronted with a citizen petition alleging statutory violations. Plaintiffs also assert that the Commissioner abused his discretion by refusing to provide them with an evidentiary hearing as a prelude to desired regulatory action. The Court cannot accept either of these arguments.

It is by now well-established that decisions of executive departments and agencies to *refrain* from instituting investigative and enforcement proceedings are essentially unreviewable by the courts. *See* e.g., *National Labor Relations Board* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 138 (1975); *Vaca* v. *Sipes*, 386 U.S. 171, 182 (1967) (noting unreviewability of decisons by the General Counsel of the NLRB not to issue an unfair labor practice complaint); *Moog Industries, Inc.* v. *Federal Trade Commission*, 335 U.S. 411, 413-414 (1958) (refusing to review FTC decision not to institute "cease and desist" proceedings pursuant to section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45); *Kixmiller* v. *Securities and Exchange Commission*, 160 U.S. App. D.C. 375, 492 F.2d 641 (1974) (judicial forum not available to review SEC staff decision not to recommend investigation or enforcement action); *Newman* v. *United States*, 127 U.S. App. D.C. 263, 382 F.2d 479 (967) (refusing to interfere with prosecutorial discretion of the United States Attorney); *Securities and Exchange Commission* v. *Tiffany Industries, Inc.*, 535 F. Supp. 1167 (E.D. Mo. 1982) (SEC refusal to join company in an enforcement proceeding not subject to judicial review). The United States Court of Appeals for the Eighth Circuit has recently confirmed that this principle of investigative and enforcement discretion is fully applicable to decisions by the Commissioner of Food and Drugs to refrain from exercising his regulatory powers in the face of petitions alleging violations of the FDC Act. *See National Milk Producers Federation* v. *Harris*, 653 F.2d 339 (8th Cir. 1981). In rejecting an effort by representatives of certain dairy producers to obtain mandatory judicial relief compelling the FDA to initiate enforcement procedures

against the manufacturers of allegedly misbranded cheese substitutes,[13] the court reaffirmed that the executive branch and its departments "enjoy a discretion in the initiation of investigative, enforcement, and prosecutorial actions limited only by constitutional strictures and relevant statutory directives." *Id.* at 343 (citations omitted). After reviewing the FDC Act, the court concluded that there was "no provision which narrows or limits the discretion of the FDA to investigate, enforce, or prosecute alleged violations of the Act or its regulations." *Id.* at 344. The Court of Appeals accordingly held that the complaint seeking mandatory declaratory and injunctive relief against the FDA for its refusal to initiate investigative, enforcement, or prosecutorial proceedings had been properly dimissed by the District Court for failure to state a claim upon which relief could have been granted.

The refusal to interfere with FDA policies of enforcement prioritization and resource allocation which underlies the *National Milk Producers* opinion is consistent with an earlier decision in this court, *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979), which declined to order the Commissioner to take affirmative steps to remove certain over-the counter drugs from the market in spite of a finding that he had exceeded his statutory authority by permitting those drugs to be marketed. In its opinion, the court expressed sympathy with the plaintiffs' frustration over the FDA's dilatory enforcement of the Drug Amendments of 1962, but noted that "plaintiffs have not attempted to demon-

[13] Alternatively, the plaintiffs sought declaratory relief establishing the illegality of the FDA's action in allegedly sanctioning the sale in interstate commerce of misbranded cheese substitutes.

strate that the Commissioner has a duty to seek enforcement action against every unlawfully marketed drug. Certainly, the statutory scheme and traditional notions of prosecutorial discretion would suggest just the opposite."[14] *Id.* at 856.

The Court can find no justification for either departing from the reasoning advanced in *National Milk Producers* and *Cutler* or fashioning an exception to that encompassing rationale out of statutory whole cloth to fit the circumstances of this case. The record indicates that plaintiffs' petition was accorded careful consideration by the Commissioner, and his reasons for declining to initiate investigative and enforcement action were fully explained in a memorandum accompanying the denial of the petition. Whether the Commissioner might have reached a different decision in light of the political, scientific, and ethical controversy surrounding the use of prescription drugs to cause death by lethal injection is of no moment; the salient point is that under established authority the decision was his to make. The Court is not prepared to dictate FDA enforcement priorities or otherwise interfere with the Commissioner's performance of his discretionary investigative functions[15] on the basis of extraneous case law arising un-

[14] It should be emphasized that ultimate enforcement authority to initiate prosecutions for alleged violations of the FDC Act resides in the Department of Justice and not the FDA. *See* 21 U.S.C. §§ 335-337. Even if the Commission had recommended enforcement action in this case, the final decision would have been left to the unfettered discretion of the Attorney General and his designated agents.

[15] Plaintiffs now contend that the commissioner's refusal to afford them an evidentiary hearing on any "controlling issue of fact" provides an appropriate basis for judicial intervention. However, it is axiomatic that a judicial order compelling the Commissioner to investigate plaintiffs' allegations through the medium of a comprehensive evidentiary hearing would have no purpose apart from serving as a prelude to the pursuit of the very enforcement steps that plaintiffs demanded in their administrative petition. Moreover, at the risk of redundancy the Court reiterates that there is *no* support for the proposition that the Commissioner *must* take specific investigative and/or enforcement steps in response to every citizen petition alleging that statutory violations have occurred. In light of the Commissioner's decision to refrain from initiating enforcement action in this case, he is not required to hold evidentiary hearings devoted to ascertaining whether these prescription drugs are safe and effective for the purpose of administering the death penalty by lethal injection.

Finally, the Court notes parenthetically that the Commissioner has been afforded considerable latitude to deny requests for hearings *in spite of* seemingly mandatory language to the contrary in the Act itself. *See, e.g., Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 619-621 (1972) (affirming Commissioner's summary withdrawal of FDA approval of a NDA despite statutory requirement in 21 U.S.C. § 355(e) of "due notice and opportunity for hearing to the applicant"); *Pineapple Growers Ass'n* v. *Food & Drug Administration*, 673 F.2d 1083 (9th Cir. 1982) (affirming Commissioner's denial of a hearing to party objecting to a revised final rule, despite requirement in 21 U.S.C. § 371(e)(3) that Commissioner "hold ... a public hearing for the purpose of receiving evidence relevant and material to the issues raised by [the] objections"); *Cooper Laboratories, Inc.* v. *Commissioner, Fed. F.D.A.*, 163 U.S. App.D.C. 212, 501 F.2d 772 (1974) (affirming summary withdrawal procedure per *Hynson, supra*). Here, by contrast, the statute is devoid of any language even intimating that the filing of a citizen petition *ipso facto* entitles the petitioner(s) to an exploratory evidentiary hearing. In fact, the pertinent regulation plainly leaves the provision of a hearing to the discretion of the Commissioner. 21 C.F.R. § 10.30(h)(2). The Court therefore disagrees with plaintiffs' suggestion that the Commissioner has "abandon[ed] his statutory duties" by declining their request for a comprehensive hearing. *See* Plaintiffs' Memorandum, at 31.

[16] *See* Plaintiffs' Memorandum, at 16-17.

der the national labor relations statutes.[16] Neither is the Court prepared to hold, as plaintiffs insist, that *United States* v. *Articles of Drug ... Beuthanasia—D Regular*, [1979 Transfer Binder] FOOD DRUG COSM L.

REP. (CCH)¶ 38,265 (D. Neb. Aug. 1, 1979) somehow compels the Commissioner to take regulatory action against those states which utilize marketed prescription drugs to execute condemned prisoners. *Beuthanasia* stands for the singularly unremarkable proposition that a substance manufactured and distributed through the channels of interstate commerce for the sole purpose of causing humane death in animals is a "drug"[17] which *may* be regulated by the FDA pursuant to its authority under 21 U.S.C. § 360b. The case provides no support whatsoever for plaintiffs' view of the Commissioner's statutory "obligation" to provide them with a public forum for airing their medical and philosophical grievances over the lethal injection procedure authorized by state law.

Finally, plaintiffs' assertion that "Congress provided no exemptions for State-mandated actions"[18] when it enacted the FDC Act is decidedly irrelevant to the legal issues presented in this lawsuit. The Court has carefully examined the letter of explanation that accompanied the Commissioner's denial of plaintiffs' petition, and does not believe that the Commissioner's decision to decline to exercise jurisdiction over an unapproved use of certain lawfully marketed prescription drugs can fairly be viewed as a blanket abdication by the FDA of its authority over all state-supervised procedures that may conflict with the specific requirements or underlying norms of the Act.[19] To restate a familiar refrain,

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[17] *See supra* p. 4, note 5.

[18] Plaintiffs' Memorandum, at 15.

[19] Neither can the Commissioner's decision be viewed as a policy statement that the Act does not afford any protection to individuals incarcerated in state penitentiaries. For example, the FDA has already taken affirmative steps to regulate clinical investigations involving prisoners as subjects. 21 C.F.R. § 50.40 (1982); *see also* 46 Fed. Reg. 61666 (Dec. 18, 1981).

the absence of a statutory exemption for state-mandated activity does not logically compel or even suggest the proffered conclusion that the Commissioner has *no* discretion to refrain from initiating requested investigative and/or enforcement proceedings under circumstances that would effectively preclude the implementation of duly enacted capital punishment statutes in Oklahoma, Texas, Idaho, and New Mexico.

CONCLUSION

To summarize, the Court is unable to perceive any "constitutional strictures" or "statutory directives" which would require the Commissioner to pursue the investigative or enforcement action that plaintiffs suggested in their petition. Having determined that the Commissioner properly exercised his discretion in denying plaintiffs' petition for relief, the Court will not proceed to recast the discretionary contours of the Federal Food, Drug and Cosmetic Act *in arbitrium judicis* to conform to personal conceptions of enlightened humanism. The defendant's motion for summary judgment will be granted, and an Order consistent with this Memorandum Opinion will be issued on this date.

/s/ Norma Holloway Johnson
NORMA HOLLOWAY JOHNSON
United States District Judge

Dated: AUGUST 30, 1982

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 81-2265

LARRY LEON CHANEY, ET AL., PLAINTIFFS,

v.

RICHARD S. SCHWEIKER, SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
DEFENDANT.

[Filed Aug. 30, 1982]

ORDER

Upon consideration of defendant's motion to dismiss or, in the alternative, for summary judgment, and plaintiffs' motion for summary judgment, the memoranda of points and authorities in support of and in opposition thereto, the affidavits, exhibits, and other supporting documentation filed by the parties, and the entire record herein, it is by the Court this 30th day of August, 1982,

ORDERED that defendant's motion in the alternative for summary judgment be, and hereby is, granted, pursuant to Fed. R. Civ. P. 56(c); and it is further

ORDERED that plaintiffs' motion for summary judgment be, and hereby is, denied; and it is further

ORDERED that this action be, and hereby is, dismissed with prejudice.

/s/ Norma Holloway Johnson
NORMA HOLLOWAY JOHNSON
United States District Judge

DEPARTMENT OF HEALTH &
HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

David E. Kendall, Esq.
Stephen M. Kristovich, Esq.
Williams & Connolly
Hill Building
Washington, D.C. 20006

July 7, 1981
Re: Docket No. 80P-0513

Dear Sirs:

This replies to your petition of December 19, 1980, as amended, regarding the contemplated use by several States of lethal injections in executing condemned inmates. Your petition notes that four States—Texas, Oklahoma, Idaho, and New Mexico—have enacted death penalty statutes that mandate the use of "lethal injection" as a means of execution. On behalf of a number of inmates who have been condemned to die by lethal injection, you request that the Food and Drug Administration (FDA) take the following actions:

1. Affix a boxed warning to the labels of the drugs specified in the State statutes stating that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

2. Prepare and send to the manufacturers of the drugs and to the prisons and departments of correction in Texas, Oklahoma, Idaho, and New Mexico notices advising that the drugs specified for use in an execution in those States' statutes or prison policies are not approved for use as a means

of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

3. Place an article in the *Drug Bulletin* advising that the drugs specified for use as lethal injections are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

4. Adopt a policy and procedure for the seizure and condemnation from prisons or State departments of correction of drugs which are intended to be used as a means of execution.

5. Recommend the prosecution of manufacturers, wholesalers, retailers, and pharmacists who knowingly sell drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess, or use drugs for the unapproved use of lethal injections.

Your petition has been carefully reviewed. For the reasons given below, we conclude that the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction and, therefore, that FDA has no authority to take the actions your petition requests. Accordingly, your petition is denied.

Our conclusion that the use of lethal injection is not subject to our jurisdiction is supported by the relevant statutory provisions, by our current policy on the use of approved drugs for unapproved uses, and by a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems.

Your petition alleges that FDA has the authority and responsibility to prevent the use of approved drugs for the unapproved use of lethal injection, and cites several

court cases as well as agency policy statements suggesting that FDA has regulatory authority over the promotion and use of drug products for purposes for which they are not shown to be safe and effective.

We agree that FDA has asserted jurisdiction over the promotion of drug products for purposes not included in the labeling for the products. In the cases cited in your petition (*United States* v. *Evers*, 453 F. Supp. 1141 (M.D. Ala. 1978); *United States* v. *An Article of Drug * * * Diso-Tate*, CCH Food Drug Cosmetic Law Reports ¶ 38.086 (E.D. La. 1976)), the agency took action to stop the promotion and use of certain products to treat disease conditions not indicated in the approved labeling for the product. The agency position on the legal status of approved labeling for prescription drugs, from which you quote extensively in your petition, was stated in a notice published in the FEDERAL REGISTER of August 15, 1972 (37 FR 16503).

Thus we do not dispute that FDA as a general matter has the authority and responsibility to regulate certain drug uses not indicated in the labeling for the products. However, we do not believe that such authority extends to the State-sanctioned use of lethal injection. The case law supports this conclusion. The Court of Appeals has now affirmed the *Evers* decision (*United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981)). This ruling, which holds that a physician does not misbrand a drug while holding it for sale after shipment in interstate commerce when he or she promotes it for an indication for which its labeling lacks adequate directions for use, has negative implications for the decision in *Diso-Tate* as well. At present, therefore, we do not be-

lieve this line of cases provides support for your petition.

Even were the contrary true, the facts on which you base your petition would still differ from the facts in these cases. Primarily, the use of drugs for execution by lethal injection is authorized by State laws in each jurisdiction. No similar laws were extant in the *Evers* and *Diso-Tate* cases. The Federal Food, Drug, and Cosmetic Act (act) defers to State law in certain areas. The drug provisions of the act do not apply, for example, to drugs wholly in intrastate commerce; their regulation is left to the States. Additionally, as reflected in the agency's notice on the legal status of approved labeling, the act does not apply to the "practice of medicine," that is, the use of approved drugs, including their use for unapproved purposes, by physicians in the treatment of individual patients. While we do not characterize the use of approved drugs for execution by lethal injection as part of the practice of medicine, we believe there is a parallel between the State's role in licensing physicians who administer drugs for both approved and unapproved purposes, and what is essentially the State's decision to use approved drugs for the purpose of execution by lethal injection.

Finally, the prescription drug provisions of the act (21 U.S.C. 353(b)) depend also on State law to define who is licensed to administer prescription drugs under the act. On the basis of these factors, we believe we must defer to a State's choice to use approved drugs for the purposes of execution by lethal injection.

We do not say, of course, that provisions of State law that are contrary to the Federal Food, Drug, and Cosmetic Act are lawful. Under the Supremacy Clause of

the Federal Constitution, for example, a State could not legitimize the unlawful shipment of an unapproved new drug in interstate commerce or prevent its misbranding after shipment in interstate commerce by authorizing its use. (*See also* section 202 of the Drug Amendments of 1962, Pub. L. 87-781, 76 Stat. 780). However, the drugs in question here are lawfully in interstate commerce at all points in time. We believe the requirements of the Federal law have been satisfied.

Were FDA clearly to have jurisdiction in the area, moreover, we believe we would be authorized to decline to exercise it under our inherent discretion to decline to pursue certain enforcement matters. The unapproved use of approved drugs is an area in which the case law is far from uniform. Generaly, enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions. Thus, as a secondary and separate basis of denial, we decline, as a matter of enforcement discretion, to pursue supplies of drugs under State control that will be used for execution by lethal injection.

Your petition also discusses *United States* v. *Beuthanasia D Regular* (CCH Food Drug Cosmetic Law Reports) ¶ 38,265 (D. Neb. 1979)), suggesting that it involves a situation "directly analogous" to the use of lethal injection in executing human beings. We do not think the situations are in fact analogous. In addition to the obvious differences in the factual settings, the finding that the drugs in that case were new animal drugs, and subject to the act, was based in part on the fact

that they were intended by their manufacturers to be used for euthanasia. No similar finding can be made here on the basis of the information before us.

Finally, your petition contains many arguments that challenge the safety of the use of these drugs as execution agents. Because we have determined that the Federal Food, Drug, and Cosmetic Act does not provide us with authority to declare unlawful the use by State governments of drugs for lethal injection, the information is not pertinent to our conclusion. It is more appropriately addressed to the State legislatures that have passed or may wish to consider this type of legislation.

Sincerely yours,

/s/ Arthur Hull Hayes, Jr., M.D.

ARTHUR HULL HAYES, JR., M.D.
Commissioner of Food and Drugs

cc:
Jack Greenberg
NAACP Legal Defense and
Educational Fund, Inc.
Anthony G. Amsterdam
Stanford University Law School

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

September Term, 1983
No. 82-2321

Civil Action No. 81-02265

LARRY LEON CHANEY, ET AL. APPELLANTS

v.

MARGARET HECKLER, AS SECRETARY OF HEALTH AND HUMAN SERVICES, APPELLEE

[Filed Jan. 17, 1984]

BEFORE: WRIGHT AND SCALIA, CIRCUIT JUDGES, AND WEIGEL*, SENIOR DISTRICT JUDGE FOR THE NORTHERN DISTRICT OF CALIFORNIA

ORDER

On consideration of the petition for rehearing of Appellee, filed December 5, 1983, it is

ORDERED by the Court that the aforesaid petition is denied.

Per Curiam
For the Court:
GEORGE A. FISHER,
Clerk

By: Robert A. Bonner

ROBERT A. BONNER
Chief Deputy Clerk

**Sitting by designation pursuant to Title 28 U.S.C. § 292(d)*

UNITED STATES COURT OF APPEALS,
FIFTH CIRCUIT

Nos. 84-2182, 84-2183

RONALD CLARK O'BRYAN, PLAINTIFF-APPELLANT

v.

DAN V. MCKASKLE, ACTING DIRECTOR, TEXAS DEPARTMENT OF CORRECTIONS, INDIVIDUALLY AND IN HIS OFFICIAL CAPACITY; ROBERT D. GUNN; JOE V. LAMANTIA, JR., HARRY M. WHITTINGTON, PETE CORTEZ, DERALYN R. DAVIS, THOMAS R. MCDADE, CLIFFORD F. SMITH, LINDSLEY WATERS, AND H. BARTEL ZACHERY, JR., INDIVIDUALLY AND AS MEMBERS OF THE TEXAS BOARD OF CORRECTIONS, DEFENDANTS-APPELLEES

RONALD CLARK O'BRYAN, PETITIONER-APPELLANT

v.

DAN V. MCKASKLE, ACTING DIRECTOR, TEXAS DEPARTMENT OF CORRECTIONS, RESPONDENT-APPELLEE.

[Filed March 29, 1984]

Applications for Leave to Appeal In Forma Pauperis, for a Certificate of Probable Cause and for a Stay of Execution Pending Appeal.

Before POLITZ, RANDALL and HIGGINBOTHAM, Circuit Judges.

PER CURIAM:

Ronald Clark O'Bryan is scheduled to be executed before sunrise on March 31, 1984. He was convicted in a Texas state court in 1975 of murdering his own child in

order to collect the proceeds from life insurance policies on his child's life. His conviction and sentence were affirmed by the Texas Court of Criminal Appeals in 1979. *O'Bryan* v. *State*, 591 S.W.2d 464 (Tex.Cr.App. 1979) (en banc), *cert. denied*, 446 U.S. 988, 100 S.Ct. 2975, 64 L.Ed.2d 846 (1980). Two applications for a writ of habeas corpus were denied by the state trial and appellate courts in 1980 and 1982, respectively. His second application for federal habeas relief (the first having been dismissed without prejudice to permit O'Bryan to return to state court to exhaust additional claims) was denied in 1982, and this court affirmed the denial of habeas relief in 1983. *O'Bryan* v. *Estelle*, 714 F.2d 365 (5th Cir. 1983), *cert. denied sub nom. O'Bryan* v. *McKaskle*, ___ U.S. ___, 104 S.Ct. 1015, 79 L.Ed.2d 245 (1984). O'Bryan's case has been before the Supreme Court on three different occasions: first, in 1980, when his petition for certiorari to review his direct appeal was denied; second, in January, 1984, when his petition for certiorari to review the decision of this court affirming the denial of federal habeas relief was denied; and third, in March, 1984, when his motion for leave to file an original petition for a writ of habeas corpus was denied, as was an accompanying motion for a stay of execution.

Following the Supreme Court's most recent action, O'Bryan elected to follow what are at least nominally two separate avenues for relief. First, he filed a new application for habeas relief in state court which was denied by the state district court on March 27, 1984, and by the Court of Criminal Appeals on March 28, 1984. O'Bryan then filed an application for federal habeas relief in federal district court, which was denied

on March 29, 1984, as were accompanying requests for a stay of execution and for a certificate of probable cause. Pending before us in connection with O'Bryan's most recent round of applications for habeas relief are applications for a certificate of probable cause and for a stay of execution.

O'Bryan's second avenue for relief consisted of filing a complaint (the "1983 Complaint") in federal district court on March 28, 1984, pursuant to 42 U.S.C. § 1983, against the Acting Director of the Texas Department of Corrections and the members of the Texas Board of Corrections (collectively, the "1983 defendants").

> (1) By failing to file an investigational new drug plan with the Food and Drug Administration ("FDA") relating to the drugs used by the 1983 defendants as a method of execution and by failing to await the results of those tests mandated by the Court of Appeals for the District of Columbia Circuit in *Chaney* v. *Heckler*, 718 F.2d 1174 (D.C.Cir.1983), *temp. stay granted* (March 21, 1984), *permanent stay granted* (March 21, 1984), *permanent stay granted* (March 30, 1984), the 1983 defendants will force O'Bryan to become an unwilling consumer of drugs that are not shown to be safe and effective for their intended use in violation of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.* (1982);
>
> (2) By failing to await the results of those tests mandated in *Chaney*, *supra*, the 1983 defendants will deprive O'Bryan of his eighth amendment right to be free from cruel and unusual punishment by subjecting him to lethal injection of drugs not proven safe, effective or humane in producing death; and

> (3) The actions of the 1983 defendants, if allowed to go unstopped, will cause O'Bryan irreparable injury for which he has no adequate remedy at law.

O'Bryan requested the district court to grant declaratory relief to the effect that the 1983 defendants' use of the drugs as a method of execution without FDA approval violates the Act and the eighth amendment and to grant preliminary and permanent injunctive relief against continuing to use the drugs as part of an execution unless expressly approved by the FDA for that purpose. On March 29, 1984, the district court denied O'Bryan's request for preliminary and permanent injunctive relief and for a stay of execution, and also denied O'Bryan's application for temporary relief pending appeal. Pending before us in connection with the 1983 Complaint is a motion to enjoin the 1983 defendants from subjecting O'Bryan to lethal injection with drugs not approved for that purpose by the FDA during the pendency of O'Bryan's appeal from the district court's judgment.

We turn first to the 1983 Complaint.[1] In general, a court, in deciding whether to issue a stay, must consider:

> (1) whether the movant has made a showing of likelihood of success on the merits, (2) whether the movant has made a showing of irreparable injury if the stay is not granted, (3) whether the granting of the stay would substantially harm

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[1] The State of Texas argues that the 1983 Complaint is a thinly-disguised habeas petition; that O'Bryan has failed to exhaust his state remedies; and that the filing of the 1983 Complaint is an abuse of the writ, citing *Jones* v. *Estelle*, 722 F.2d 159 (5th Cir.1983) (en banc). In view of the result that we reach, we do not decide those questions.

the other parties, and (4) whether the granting of the stay would serve the public interest.

Ruiz v. *Estelle*, 666 F.2d 854, 856 (5th Cir. 1982) (*Ruiz II*) (quoting *Ruiz v. Estelle*, 650 F.2d 555, 565 (5th Cir.1981) (Ruiz I)). While "the movant need not *always* show a 'probability' of success on the merits," he must "present a substantial case on the merits when a serious legal question is involved and show that *the balance of equities*, [i.e. the other three factors] *weighs heavily in the favor of granting the stay.*" *Ruiz II*, 666 F.2d at 856 (emphasis in original) (quoting *Ruiz I*, 650 F.2d at 565). Insofar as the likelihood of success on the merits is concerned, we do not think that O'Bryan has made the showing required for a stay. We begin by noting that the mandate in *Chaney* v. *Heckler*, *supra*, has not issued, having been stayed by Chief Justice Burger pending the government's application for a writ of certiorari in the Supreme Court. We note also that neither this court nor any party to this case is bound by the decision of the Court of Appeals for the District of Columbia Circuit in *Chaney*. On the probable merits of O'Bryan's claim of a violation of the Act, we think that, for the reasons set forth in Judge Scalia's dissenting opinion in *Chaney*, O'Bryan's claim is insubstantial and

he is unlikely to succeed on appeal.[2] *See also United States* v. *Evers*, 643 F.2d 1043 (5th Cir.1981).

Insofar as his second claim is concerned—that by failing to await the results of the tests mandated in *Chaney*, the 1983 defendants will deprive O'Bryan of his eighth amendment right to be free from cruel and unusual punishment—we agree with the State that the showing made by O'Bryan of discomfort or unnecessary pain falls far short of the showing found insufficient in *Gray* v. *Lucas*, 710 F.2d 1048 (5th Cir.1983). Accordingly, O'Bryan's probability of success on the merits of this claim is inadequate to justify a stay.

Finally, turning to O'Bryan's most recent round of applications for habeas relief, the district court, in a careful opinion, held that O'Bryan's petition was a successive petition governed by Rule 9(b) of the Rules Governing Section 2254 Cases in the United States District Courts, alleging no new or different grounds for relief from his earlier federal court petition which was decided on the merits. The court noted that Rule 9(b) was designed to afford the district court discretion in reviewing a successive claim and to make redetermina-

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[2] Although not argued by the parties, we are unable to identify the legal footing for O'Bryan's present effort to enforce this detailed federal administrative scheme. *Middlesex County Sewerage Authority* v. *National Sea Clammers Assoc.*, 453 U.S. 1, 101 S.Ct. 2615, 69 L.Ed.2d 435 (1981); *Great American Federal Savings & Loan Assoc.* v. *Novotny*, 442 U.S. 366, 99 S.Ct. 2345, 60 L.Ed.2d 957 (1979); *Brown* v. *General Services Administration*, 425 U.S. 820, 96 S.Ct. 1961, 48 L.Ed.2d 402 (1976); *Adickes* v. *S.H. Kress & Co.*, 398 U.S. 144, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970). Moreover, Congress provided in the Act that "[a]ll such proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States." 21 U.S.C. § 338.

tions where "the applicant shows that the ends of justice would be served by permitting redeterminations of the ground," *citing Sanders* v. *United States*, 373 U.S. 1, 16, 83 S.Ct. 1068, 1078, 10 L.Ed.2d 148 (1963). The district court held that O'Bryan's current habeas petition presents no arguments that have not already been presented to this court and twice to the Supreme Court and rejected by all, and that the ends of justice would not be served by permitting redeterminations of those arguments.

We are governed in this case by the Supreme Court's recent opinion in *Barefoot* v. *Estelle*, ____ U.S. ____, 103 S.Ct. 3383, 77 L.Ed.2d 1090 (1983). Specifically, in order to obtain a certificate of probable cause, O'Bryan must make a "'substantial showing of the denial of [a] federal right.'" 103 S.Ct. at 3394. He must demonstrate that the issues raised in his application for federal habeas relief are "debatable among jurists of reason; that a court could resolve the issues [in a different manner]; or that the questions are 'adequate to serve encouragement to proceed further.'" *Id.* 103 S.Ct. at 3394 n. 4 (quoting *Gordon* v. *Willis*, 516 F.Supp. 911, 913 (N.D.Ga.1980)). We think that O'Bryan has failed to make that showing.

The application in No. 84-2182 for leave to appeal in forma pauperis is GRANTED; the application in that case for a stay of execution is DENIED. The applications in No. 84-2183 for leave to appeal in forma pauperis, for a stay of execution and for a certificate of probable cause are DENIED. The mandate shall issue forthwith.

STATUTES

5 U.S.C. 701(a) provides in pertinent part:

This chapter applies, according to the provisions thereof, except to the extent that—

(1) statutes preclude judicial review; or

(2) agency action is committed to agency discretion by law.

21 U.S.C. 331 provides in pertinent part:

The following acts and the causing thereof are prohibited:

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

21 U.S.C. 352 provides in pertinent part:

A drug or device shall be deemed to be misbranded—

* * * * *

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are neces-

sary for the protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

OPPOSITION BRIEF

ORIGINAL

(10)

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No. 83-1878

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1983

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL., RESPONDENTS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

MEMORANDUM IN RESPONSE TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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QUESTIONS PRESENTED

1. Whether the Administrative Procedure Act, 5 U.S.C. §§ 701-706, authorizes judicial review of the Food and Drug Administration's ("FDA") decision not to enforce the Food, Drug, and Cosmetic Act ("FDCA") with regard to the states' use of drugs in violation of the Act for the unapproved use of lethal injection.

2. If the courts have the authority to review the FDA's decision not to enforce the FDCA with regard to the states' use of drugs for lethal injection, whether the FDA's decision not to enforce the Act to ensure that the drugs used would effect a quick and painless death was arbitrary and capricious.

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1983

No. 83-1878

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL., RESPONDENTS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

MEMORANDUM IN RESPONSE TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Respondents Larry Leon Chaney, Alton Franks, Carl Morgan, Charles W. Davis, Robyn Parks, Doyle Skillern, Jerry Joe Bird, and Henry Martinez Porter,[1/] by counsel, hereby respond to the government's petition for a writ of certiorari to review the opinion of the Court of Appeals for the District of Columbia Circuit in this case (Pet. for Cert. App. 1a-58a) reported at 718 F.2d 1174.

1/ Since this law suit was filed, respondent Chaney's death sentence has been reversed by the United States Court of Appeals for the Tenth Circuit and he has been remanded for resentencing (Chaney v. Brown, No. 83-1867 (March 21, 1984)(slip op.)), respondent Franks' conviction has been reduced to second degree murder and his sentence of death vacated (Franks v. State, 636 P.2d 361 (Okla. Ct. Crim. App. 1981)), and respondent Morgan's sentence of death has been vacated (Morgan v. State, No. F79487 (Okla. Ct. Crim. App.)(November 15, 1983)(slip op.)).

Statutes Involved

Relevant provisions of the Administrative Procedure Act ("APA") and the Food, Drug, and Cosmetic Act ("FDCA") not reprinted in the appendix to the government's petition for a writ of certiorari, Pet. for Cert. App. 95a-96a, are reprinted at App., infra, 87a-93a.

STATEMENT

Since 1977, fourteen states[2/] have enacted statutes mandating the use of certain drugs for a radically new purpose: the execution of human beings by lethal injection. Prisons in these fourteen states currently house 392 persons under sentence of death. Respondents were sentenced to be executed under the Oklahoma and Texas statutes.

The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. §§ 301 et seq., prohibits the interstate distribution of a "new drug" (including any previously known drug that is being used for a new purpose) unless the Secretary of Health and Human Services has approved an application supported by substantial evidence of the drug's safety and effectiveness for its specified purpose. 21 U.S.C. § 355(a). The FDCA also prohibits the misbranding of any drug in interstate commerce, 21 U.S.C. § 331(b), and any act with respect to a drug which "is done while such [drug] is held for sale (whether or not the first sale) after shipment in interstate commerce and [which] results in such article being . . . misbranded." 21 U.S.C. § 331(k).

The Secretary of Health and Human Services and her agents have not issued approvals for the use of any drug for the

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2/ Massachusetts and South Dakota, in addition to the twelve states cited by the government in its petition for a writ of certiorari (Pet. for Cert. 2 n.1), have also enacted lethal injection statutes. Mass. Gen. Laws Ann. ch. 279, § 60 (choice of electrocution or lethal injection); S.Dak. S.B. 158, effective February 29, 1984.

lethal injection of a human being. Therefore, lethal injection involves the untested and unapproved use of drugs manufactured, distributed and sold in interstate commerce for the non-medical purpose of killing human beings. In a directly analogous case initiated by the FDA, a district court in Nebraska held that relevant criteria in assessing the safety and effectiveness of drugs used by veterinarians to kill domestic animals included (1) the drug's ability to cause death without pain and discomfort; (2) the time required to produce loss of consciousness; (3) the time required to produce death; and (4) the reliability of the drug to obtain consistently effective results. United States v. Beuthanasia-D. Regular, [1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 at 39,139 (D. Neb. 1979). In essence, "safe and effective" in the context of drugs used for lethal injection means quick and painless.

In December 1980, respondents, all of whom were under sentence of death by lethal injection for the crime of murder, petitioned the Secretary of Health and Human Services in accordance with 21 C.F.R. § 10.30 to enforce the FDCA and to prevent the unapproved use of drugs for lethal injection. Respondents also requested an evidentiary hearing on any controlling issue of fact.

Respondents' administrative petition, App., infra, 13a-84a, contained a detailed recitation of the known evidence concerning lethal injection, which indicates that there is strong evidence that the lethal injection of drugs is not a "safe and effective" means of executing people and that its use poses a substantial threat of torturous pain to persons being executed. Respondents appended to their petition affidavits of leading medical and scientific experts[3/] which aver that there is by no

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3/ Two of the affiants are accomplished anesthesiologists familiar with the drugs specified for use in lethal injection as

means an "expert consensus" founded upon "substantial evidence" consisting of "adequate and well-controlled investigations," including "clinical investigations," that the drugs to be used to execute people will have the effect they purport or are represented to have, to wit, that they will produce loss of consciousness and death quickly and without pain and discomfort. App., infra, 55a-58a, 64a-67a. These experts are not aware of any published scientific data or information which in any respect addresses the use of these drugs as a means of execution, much less establishes their effectiveness. Id. Nor are these experts aware of any adequate and well-controlled investigations establishing the effectiveness of these drugs for a lethal injection. Id.

In their affidavits, these experts explain why the successful administration of a painless lethal injection and the determination of the correct dosage of drugs to be used would be very difficult even for the most highly trained and experienced of physicians. Id. In practice, however, the risks of improper administration or determination of dosage in the context of lethal injections are substantially greater because highly trained expert physicians and other health professionals will not -- indeed, legally and ethically cannot -- participate in such activity. As explained in the affidavit of a physician who has written on the subject of medical ethics, App., infra,

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Footnote 3 continued:

well as with the "intravenous" injection procedure mandated by the statutes and their interpreting regulations. One affiant is a former president of the Florida Medical Association. App., infra, 53a-61a. The second affiant is Professor of Anesthesia, Emeritus, at Harvard Medical School, Anesthesiologist to Boston's Peter Bent Brigham Hospital, and Director of Anesthesiology at the Hospital at Parker Hill in Boston, a hospital run by the Harvard Community Health Plan. App., infra, 64a-82a.

42a-46a, participation of a physician in an execution by lethal injection, be it through the ordering of the drugs, the preparation of the dosage, the actual administration of the injection or the supervision of others in carrying out these tasks, would be in violation of the physicians' Hippocratic Oath, the ethical guide of the medical profession for 2,500 years, which provides:

> To please no one will I prescribe a deadly drug, nor give advice which may cause his death.

The American Medical Association and professional medical societies in several states with lethal injection statutes have passed or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a legally authorized execution other than to make a determination or certification of death. Id. at 42a-44a.

Finally, respondents submitted an affidavit which avers that the licensing laws and ethical standards for nurses and medical technicians would also prevent them from carrying out a lethal injection. Id. at 45a-46a. This is so not only because all health professionals adhere to their own versions of the Hippocratic Oath, but also because such personnel do not have the authority to prepare or administer a drug dosage independent of a physician's specific order or valid standing orders, which orders, of course, could not ethically or legally be forthcoming from doctors. Id. Furthermore, such personnel would be even less experienced than physicians in carrying out drug injections since they would be less likely to have worked with laboratory animals. Id.

In short, respondents demonstrated in their petition that lethal injection necessarily involves the use of untested and unapproved drugs to kill people, administered not by trained physicians or other health professionals in their practice of medicine, but by untrained, nonprofessional personnel.

In July 1981, the Secretary's agent, the Commissioner of the Food and Drug Administration ("FDA"), sent counsel for respondents a letter (hereinafter "Commissioner's Letter"), Pet. for Cert. App. 83a-88a, summarily rejecting respondents' petition without affording them an evidentiary hearing, and refusing to take any of the action sought by the petition. FDA Commissioner Arthur Hull Hayes conceded that "FDA as a general matter has the authority and responsibility to regulate certain drug uses not indicated in the labeling for the products." Id. at 85a. Nevertheless, Commissioner Hayes continued, "we do not believe that such authority extends to the State-sanctioned use of lethal injection." Id. Therefore, the FDA denied respondents' petition on two separate and distinguishable grounds: (1) "the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction and, therefore, . . . FDA has no authority to take the actions your petition requests," Id. at 84a; and (2) if FDA had jurisdiction, "we would be authorized to decline to exercise it under our inherent discretion to decline to pursue certain enforcement matters," Id. at 87a.

In September 1981, respondents filed a complaint (App., infra, 1a-89a) seeking declaratory relief and an order compelling the Secretary of Health and Human Services to take the requisite steps to enforce the Act and prohibit the unapproved use of drugs in state-mandated lethal injections. After limited discovery, respondents and the Secretary filed cross-motions for summary judgment.

The district court issued an opinion and order (Pet. for Cert. App. 63a-80a) denying respondents' summary judgment motion and granting that of the Secretary on August 30, 1982. The district court held that the "Commissioner's decision to refrain from interfering with the implementation of state capital punishment statutes constitutes a defensible exercise of his considerable investigative and enforcement discretion under the F.D.C. Act." Id. at 64a. This was the sole ground upon which the district court's opinion is based. The district court declined to rule upon the FDA's determination that it does not have jurisdiction to require states to comply with the requirements of the FDCA regarding drugs used in lethal injections. Id. at 73a.

On October 14, 1983, the court of appeals, with Judge Scalia dissenting, vacated the district court judgment and remanded "with instructions to order the agency to fulfill its statutory function." Id. at 36a. Both the majority and the dissent (Id. at 9a-12a, 54a) rejected the government's argument below that, because state penal systems like physicians are licensed by the states, the unapproved use of drugs for lethal injection is within the "practice-of-medicine" exemption from FDA jurisdiction for state-regulated activity. The court of appeals observed that the "FDA has in fact regulated drugs used in prison clinical investigations . . . and in veterinary practices . . ." and that in "both situations FDA has rejected arguments that it does not have authority to regulate unapproved uses of approved drugs." Id. at 12a (citations omitted).

The court of appeals held that the use of drugs as a means of execution results in their being "misbranded" and therefore in violation of 21 U.S.C. § 331(b), which prohibits any misbranding in interstate commerce. The court of appeals noted

that current understanding of Congressional power under the Commerce Clause would cover state prisons' use of drugs shipped in interstate commerce. Id. at 14a. In addition, the court of appeals found a violation of 21 U.S.C. § 331(k), which prohibits any action taken upon a drug while such article is held for sale after shipment in interstate commerce and results in the article being misbranded. Id. at 14a-17a. The court of appeals observed that Congress enacted the "held for sale" provision of Section 331(k) in 1938 to expand the FDCA to apply to each stage of the distribution process from the manufacturer to the ultimate user of the drug. Id. at 14a-15a. The court of appeals also acknowledged the FDA's admission that it has jurisdiction over all state laws "'that purport[] to legitimize the lawful shipment of an unapproved drug in interstate commerce, or that purport[] to permit its misbranding after shipment * * *.'" Id. at 16a. The court of appeals held that since state lethal injection statutes do precisely this, i.e., mandate the use of prescription drugs for a purpose not listed on their label, the drugs are misbranded and therefore within the jurisdiction of the FDA.

The court of appeals held that this Court's admonishment to "construe narrowly the 'committed to agency discretion' exception of Section 10 of the Administrative Procedure Act ("APA"), 5 U.S.C. § 701(a)(2) (1982), and 'to find it applicable only in those rare instances where the governing statute is drawn in such broad terms that in a given case there is no law to apply,'" applies with equal force to the review of agency enforcement decisions. Id. at 21a-22a. Therefore, the court of appeals rejected the government's argument that the FDCA gives the FDA absolute discretion over enforcement decisions. Id. at 17a-38a.

In determining whether there was "law to apply" to the FDA decision not to enforce the FDCA to ensure that drugs used for lethal injection will effect a quick and painless death, the court of appeals considered "whether judicial supervision is necessary to safeguard plaintiffs' interests, whether judicial review will unnecessarily impede the agency in effectively carrying out its Congressionally assigned role, and whether the issues are appropriate for judicial review." Id. at 24a. The court of appeals found that a policy statement, adopted by the FDA in 1972 and conceded by the FDA to be the current agency position as to what the FDCA requires, sets forth the FDA's position on the unapproved use of approved drugs:

> Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. * * * When necessary the Food and Drug Administration will not hesitate to take whatever action * * * may be required to bring possible harmful use of an approved drug under control.
>
> * * * Thus, where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly.

Id. at 24a-25a. In addition, the court of appeals found that the express terms of the statute as well as a growing body of case law interpreting the statute provided it with "more than enough law to apply" to the FDA's decision here, and that therefore this decision is subject to judicial review. Id. at 25a-26a.

Based upon its "searching and careful" review of the administrative record and the agency's stated reasons for

inaction, the court of appeals held that the FDA's decision was arbitrary, capricious, and without authority of law. Id. at 30a-35a. First, the court of appeals found that the Commissioner's claim that his legal authority in this area is uncertain is irrational in light of the 1972 policy statement and the agency's prior assertion of jurisdiction over drugs used in state-licensed clinical investigations with prisoners and in state-licensed veterinary practices to kill animals. Second, in light of the uncontroverted evidence submitted to FDA by respondents which shows that drugs used in lethal injection pose a substantial threat of torturous pain to hundreds of persons under sentence of death by lethal injection, the court of appeals rejected the agency's claim that these drugs do not pose a serious danger to the public health:

> [T]his claim rationally cannot stand next to FDA's earlier assertion that prisoners in clinical investigations and dogs in veterinary clinics were in "serious danger" from the unapproved use of approved drugs. If drugs used in these contexts pose a "serious threat" to the public health, then certainly drugs used to kill human beings pose such a threat.

Id. at 34a.

The government filed a suggestion for rehearing en banc which was denied by an equally divided court of appeals.

ISSUES RAISED BY THE PETITION FOR CERTIORARI

The government offers three reasons (Pet. for Cert. 6-7) in support of its petition for certiorari:

1. the court of appeals' decision conflicts with the decisions of two other circuits;

2. it unduly interferes with the FDA's enforcement discretion; and

3. it unduly interferes with the states' exercise of their power to enforce their criminal laws.

The third "reason" is nothing more than a variation of the argument made by the FDA below that state-licensed activity is exempt from FDA jurisdiction. Therefore, this "reason" will be addressed in the discussion of judicial review of agency enforcement decisions.

This case raises difficult and thorny issues. Moreover, it presents a significant public policy question with implications for the scope of authority of all federal agencies. This policy question, however, is not the one identified by the government in its brief as a clash between the Executive and Judicial branches. Rather, the conflict presented is that between the Executive and Legislative branches.

This case presents the question whether an administrative agency may "arbitrarily and capriciously refuse to exercise its regulatory jurisdiction." Pet. for Cert. App. 4a. At issue in this case is the extent to which there is judicial review of executive abnegation of a Congressional mandate of enforcement responsibility.[4/] Simply put, the question is whether the executive can implement a "deregulatory" decision under the guise of enforcement discretion despite a contrary legislative mandate. Both the Solicitor General and the dissent below attempt to finesse this substantial and thorny policy question.[4a/]

4/ This Court has repeatedly condemned attempts by agencies to administratively amend statutes by engrafting exemptions onto them. See, e.g., Leedom v. Kyne, 358 U.S. 184 (1958); Hotel Employees Local No. 255 v. Leedom, 358 U.S. 99 (1958); Office Employees International Union, Local No. 11 v. NLRB, 353 U.S. 313 (1957).

4a/ In the last few years, the country has taken the first tentative steps into what may be a new era of deregulation. As part of this process, there has been, and continues to be, (Footnote Continued)

While certain enforcement priorities must necessarily be set in the light of budgetary considerations and resource availability, the FDA's decision to abjure responsibility[5/] for regulating the lethal injection of humans was not dicated by such practical considerations. Although the Solicitor General now claims that the FDA "acted reasonably in conserving its limited enforcement resources" (Pet. for Cert. 14), this is the first time that the agency has argued that budgetary considerations were a factor in its decision. As noted by the court of appeals, the "Commissioner has not asserted, at any point, that budgetary constraints would prevent FDA from investigating and taking appropriate action." Pet. for Cert. App. 33a n.42. Courts properly review agency decisions only on the basis of the agency's stated reasons, and not on subsequent rationalizations of counsel. Burlington Truck Lines, Inc. v. United States, 168-169, 371 U.S. 156, 168-169 (1962). Moreover, courts have rejected such arguments where Congress or the agency has promised

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a significant debate throughout the government and the public at large about the appropriateness and scope of deregulation. Ultimately, however, it is the judgment of Congress that determines and articulates, through legislation, the outcome of this ongoing debate.

Congress has, in some instances, enacted legislation removing some of the strictures it had previously placed on certain segments of society. In other instances, Congress has been hesitant to proceed with even the slightest reduction of the regulatory framework it had previously created. Faced with this sometimes hesitant Congress, administrative agencies on occasion are attempting on their own to reduce or eliminate their regulatory role. The danger posed by such unilateral agency action is that the agency will overstep its bounds and take action contrary to Congressional intent.

5/ Indeed, FDA's initial contention -- now abandoned in this court -- was that its regulatory jurisdiction did not extend to review of state-sanctioned lethal injection. Pet. for Cert. App. 7a, 8a, 13a. The court below concluded, and the government does not gainsay, that the FDA "must have jurisdiction to regulate such activity." Pet. for Cert. App. 17a (emphasis added, footnote deleted).

that action will be taken, as is the case here. See, e.g., Adams v. Califano, D.D.C. Civil Action No. 70-3095 (Dec. 29, 1977); Hoffman-LaRoche, Inc. v. Weinberger, supra, 425 F.Supp. 890 (D.D.C. 1975); American Public Health Association v. Venema, supra, 349 F.Supp. 1311 (D.D.C. 1972).

Thus, at issue in this case is "FDA's decision to take no action -- either investigatory or regulatory -- against the unapproved use of approved drugs in state capital punishment systems," Pet. for Cert. App. 3a (emphasis in original), despite Congress' clear intent that the FDA's remedial provisions be construed broadly.[6/] In

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6/ See, e.g., United States v. Rutherford, 442 U.S. 544, 552-554 (1979); United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969); United States v. Sullivan, 332 U.S. 689, 693 (1948).

short, the issue is one of executive usurpation of Congressional authority. The danger posed by such unilateral agency action is magnified here by the fact that the statute at issue was enacted by Congress for the protection of individuals, including those whom the agency has now removed from the Act's coverage.

1. Conflict in the Circuits

The government correctly observes that the decision below "squarely conflicts" with the Fifth Circuit's recent decision in O'Bryan v. McKaskle, 729 F.2d 991 (1984), Pet. for Cert. App. 88a-94a. The plaintiff in that case was a Texas prisoner who filed a complaint pursuant to 42 U.S.C. § 1983 against various state officials seeking a declaration that the defendants' intent to use drugs in the lethal injection of plaintiff violates the FDCA and an injunction preventing the use of drugs for this purpose until expressly approved by the FDA. The Fifth Circuit held that O'Bryan's claims under the FDCA were "insubstantial" and that "he is unlikely to succeed on appeal." Pet. for Cert. App. 92a-93a. However, unlike the court of appeals in this case, the Fifth Circuit did not have the benefit of the administrative record and complete briefing on the relevant issues or the luxury of time to analyze the difficult questions these issues pose, since Mr. O'Bryan's case was filed at the eleventh hour and the court's decision was issued almost immediately, shortly prior to his execution. The court of appeals below correctly applied this Court's prior controlling decisions to the FDA's inaction based upon the compelling record before it.

The second case that the government contends presents a "square conflict," National Milk Producers Federation v. Harris, 653 F.2d 339 (8th Cir. 1981), is plainly distinguishable,

however. The court of appeals correctly observed that this case does "not hold that courts cannot review FDA's complete refusal to investigate and regulate an entire class of drugs." Pet. for Cert. App. 29a n.35. In National Milk Producers, the FDA had held lengthy notice and comment rulemaking proceedings and other rulemaking proceedings over a number of years in which plaintiffs had participated. The result of these proceedings was an elaborate set of regulations. Plaintiffs sued to try to force FDA enforcement action against certain manufacturers subject to these regulations. The Eighth Circuit ruled that the FDA's interpretation of its own regulations was entitled to deference[7] by the courts and that it had acted within its power when it set enforcement practices within budgetary and other constraints. Thus, the Eighth Circuit in National Milk Producers reviewed and accepted FDA's decision -- good faith budgetary constraints -- for not enforcing certain regulations. In rejecting respondents' petition, the Commissioner in this case did not raise good faith budgetary constraints.[8] Pet. for Cert. App. 81a-86a. To the

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7/ In this case, unlike the situation in National Milk Producers, "FDA's determination that it does not have jurisdiction over drugs used in lethal injections is entitled to only the most limited deference because it is inconsistent with longstanding FDA and court interpretation of the Act. See FEC v. Democratic Senatorial Campaign Committee, 454 U.S. 27, 37 (1981); Zenith Radio Corp. v. United States, 437 U.S. 443, 450 (1978)." Pet. for Cert. App. 17a n.21.

8/ "The Commissioner has not asserted, at any point, that budgetary constraints would prevent FDA from investigating and taking appropriate action. While we have no occasion to address this hypothetical explanation, we do note that other courts have rejected it in situations where Congress (or the agency) has promised that action will be taken." Pet. for Cert. App. 33a n.42 (citations omitted).

With the hope of buttressing the FDA's inadequate, stated grounds for rejecting respondents' petition, the government now, for the first time, suggests that the FDA's decision was reasonable because it "conserv[ed] its limited enforcement resources." Pet. for Cert. 14. Courts properly review agency action or nonaction on the basis of the agency's stated reasons, and not on subsequent rationalizations of government counsel. Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168-169 (1962).

contrary, here the FDA refuses to take any steps of any kind, including holding a hearing to enable it to exercise its jurisdiction in an informed fashion with regard to the safety and effectiveness of lethal injection drugs, disclaiming jurisdiction over the entire subject.9/

2. **Judicial Review of Agency Enforcement Decisions**

A. **FDA's Enforcement Decision is Subject to Judicial Review.**

The government argues that the court of appeals decision holding that the FDA's decision not to enforce the FDCA with regard to the unapproved use of drugs for lethal injection "departed dramatically from settled principles of administrative law." Pet. for Cert. 8. To the contrary, the decision is consistent with the controlling law of this Court.

The APA provides that all agency action is subject to judicial review unless precluded by statute or committed to agency discretion. 5 U.S.C. § 701(a)(1), (2). Judicial review will not be cut off "unless there is persuasive reason to believe that such was the purpose of Congress." Abbott Laboratories v. Gardner, 387 U.S. 136, 140. "[O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." Id. at 141. See also Dunlop v. Bachowski, 421 U.S. 560, 567 (1975); Rusk v. Cort, 369 U.S. 367, 377-380 (1962). The exception for "agency action committed to agency discretion" is a "very narrow exception . . . applicable in those rare instances when 'statutes are drawn in such broad terms that in a given case there is no law to apply.'" Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 410 (1971) (quoting S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945).).10/

Despite these repeated, consistent statements that judicial review is favored, the government argues that "agency enforcement decisions are not subject to judicial review, absent special circumstances." Pet. for Cert. 9.11/ But in Dunlop v. Bachowski, supra, 421 U.S. 560 (1976), the circumstances were

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9/ In this case, the "FDA refused to take any action with regard to an entire category of allegedly prohibited activity. Courts are especially willing to review agency lassitude (or recalcitrance) of this magnitude." Pet. for Cert. App. 35a n.45 (emphasis in original) (citations omitted).

10/ See also Dunlop v. Bachowski, supra, 421 U.S. at 567 and n.7 (1975); Abbott Laboratories v. Gardner, supra, 387 U.S. at 140-141 (1967); WWHT, Inc. v. FCC, 656 F.2d 807, 809, 815 (D.C. Cir. 1981); Natural Resources Defense Council, Inc. v. SEC, 606 F.2d 1031, 1043 (D.C. Cir. 1979).

11/ The cases relied upon by the government do not support this sweeping proposition. In Southern Railway Company v. Seabord Allied Milling Corp., 442 U.S. 444 (1979), the Court held that an ICC decision not to order a hearing to investigate the lawfulness of a proposed rate increase was not subject to judicial review. The Court's holding, however, was not based upon a belief that agency enforcement decisions are unreviewable in general. To the contrary, the Court began its analysis by stating that "we will not lightly interpret a statute to confer unreviewable power on an administrative agency," 442 U.S. at 454, citing Dunlop v. Bachowski, 421 U.S. 560, 567 (1976). The Court proceeded to determine congressional intent as to the reviewability of the particular matters at issue. Based upon its review of the "language, structure, and history of the [Interstate Commerce] Act," the Court found that Congress intended the agency decision to be nonreviewable, in part because there was "'no law to apply' in determining if the decision is correct." 442 U.S. at 455. In this case, there is no evidence Congress intended to grant FDA unreviewable power in the enforcement area. Moreover, there are legal standards against which to measure FDA's decision. Finally, the Court observed in making its finding of nonreviewability in Southern Railway that the agency decisions at issue do not "affect[] any citizen's ultimate rights." Id. The FDA's decision here, on the other hand, directly affects respondents' rights.

In Vaca v. Sipes, 386 U.S. 171 (1967), the Court in dicta stated that the General Counsel of the National Labor Relations Board has unreviewable discretion to refuse to initiate an unfair labor practice complaint. The latter case of NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 138 (1975), however, makes clear that this agency discretion was unreviewable because of the express preclusive statutory command of 29 U.S.C. § 153(d), 421 U.S. at 138, and not as a result of any generalized presumption against the review of agency enforcement decisions.

neither atypical nor extraordinary, and this Court held that an agency decision not to take enforcement action was reviewable.

In Dunlop, the unsuccessful candidate for union office asked the Secretary of Labor to investigate his claims of election fraud and to bring a civil action to set aside the election if warranted pursuant to the Labor-Management Reporting and Disclosure Act, 29 U.S.C. § 482. When the Secretary refused to take action on the complaint, the defeated candidate sought judicial review of the Secretary's decision not to enforce the statute. The Secretary argued that his action was unreviewable under both the precluded-by-statute and committed-to-agency-discretion exceptions of the APA, 5 U.S.C. § 701(a)(1), (2). The Court held that neither exception applied, and that the Secretary's decision to refrain from exercising enforcement power was reviewable. In rejecting the Secretary's claim that his nonenforcement decision was an unreviewable exercise of discretion, the Court adopted the reasoning of the lower court.

In Bachowski v. Brennan, 502 F.2d 79 (3rd. Cir. 1974), the circuit court held that the Secretary's decision was reviewable for two reasons. First, "the doctrine of prosecutorial discretion should be limited to those civil cases which, like criminal prosecutions, involve the vindication of societal or governmental interest, rather than the protection of

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Footnote 11 continued:

United States v. Batchelder, 442 U.S. 114 (1979) and Bordenkircher v. Hayes, 434 U.S. 357 (1978), involved prosecutorial discretion in criminal matters, an area which the court of appeals expressly acknowledged "received the maximum degree of judicial deference." Pet. for Cert. App. 28a n. 35. However, in their administrative petition, App., infra, 30a-31a, respondents only requested the FDA to take steps to notify drug manufacturers, physicians, prisons and departments of corrections that the drugs had not been approved as a means of execution and therefore should not be used for this purpose, and to adopt a policy and procedure for the civil enforcement of the FDCA through the seizure and condemnation of these drugs when held for use in lethal injection. The petition also asked the FDA to "[r]ecommend the prosecution" of individuals who knowingly violated the Act with regard to the unapproved use of these drugs. Id. (Emphasis added.)

individual rights." 502 F.2d at 87. Second, the Secretary's conduct could be measured against appropriate legal standards. Id. at 88.

The court of appeals in this case correctly observed that no language in the court of appeals decision in Bachowski supports the government's claim that the court considered that case atypical or extraordinary in any way. Pet. for Cert. App. 23a n. 26. Moreover, the court of appeals found that the two factors relied upon by the Third Circuit in Bachowski "apply with equal force to the present controversy." Pet. for Cert. App. 23a and n.26. Congress intended the FDCA to protect the individuals on whom drugs are used. In addition, there are legal standards against which to measure the FDA action here.[12] Id.

In determining whether there was, in the words of Overton Park, "law to apply," the court of appeals found that the FDA's 1972 policy statement, the express language of the statute and the applicable case law "provide[] this Court with more than enough law to apply."[13] Pet. for Cert. App. 26a.

12/ The government's bald assertion that the court of appeals in Bachowski v. Brennan, 502 F.2d 79 (3rd Cir. 1974), "noted that the exercise of enforcement discretion is generally unreviewable," Pet. for Cert. 10 n.7, is simply wrong. The language in the opinion neither states nor implies that there is a general presumption against review. In point of fact, the tenor of the opinion and its holding are directly to the contrary.

13/ The court of appeals observed that determining "whether there is 'law to apply' turns on such pragmatic considerations as whether judicial supervision is necessary to safeguard plaintiffs' interests, whether judicial review will unnecessarily impede the agency in effectively carrying out its Congressionally assigned role, and whether the issues are appropriate for judicial review." Pet. for Cert. App. 24a. However, in light of the clear standards applicable to the FDA's decision, as set forth in the 1972 policy statement, the statute itself and the case law, the court of appeals found that it "need not delve into a detailed analysis of nonreviewability." Id. Nevertheless, the government characterizes the court of appeals' recitation of considerations as "startling," Pet. for Cert. 11. The court of appeals' analysis is consistent with the analysis used by the

The 1972 policy statement expressly provides, in the agency's own words, that "[w]here the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. . . . When necessary the Food and Drug Administration will not hesitate to take whatever action . . . may be required to bring possible harmful use of an approved drug under control." The FDA admitted in its papers below that this policy statement sets forth the agency's current position with regard to the unapproved use of approved drugs, Pet. for Cert. App. 24a, and in rejecting respondents' petition, the Commissioner conceded that the "FDA as a general matter has the authority and responsibility to regulate certain drug uses not indicated in the labeling for the products," Pet. for Cert. App. 83a.

The government now characterizes this policy statement as merely a preamble to a rule that the agency never adopted. Pet. for Cert. 11. However, the agency itself still considers this statement of policy "binding and to have substantive

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Footnote 13 continued:

courts of appeal in several other circuits, and by other panels of the court of appeals in this circuit. See, e.g., Falkowski v. Equal Employment Opportunity Commission, 719 F.2d 470, 480-481 n.16 (D.C. Cir. 1983); Tuepker v. Farmers Home Administration, 708 F.2d 1329, 1332 (8th Cir. 1983); Local 1219, American Federation of Government Employees v. Donovan, 683 F.2d 511, 515 (D.C. Cir. 1982); Sinai Hospital of Baltimore v. Horvitz, 621 F.2d 1267, 1270 (4th Cir. 1980); Local 2855, American Federation of Government Employees (AFL-CIO) v. United States, 602 F.2d 574, 578 (3rd Cir. 1979); Natural Resources Defense Council, Inc. v. S.E.C., 606 F.2d 1031, 1044 (D.C. Cir. 1979); Davis Associates, Inc. v. Secretary, Department of Housing and Urban Development, 498 F.2d 385, 390 (1st Cir. 1974); Kletschka v. Driver, 411 F.2d 436, 443 (2d Cir. 1969). Such an analysis does not, as the government argues, convert statutory interpretation into a "standardless, legislative decision." Pet. for Cert. 11. To the contrary, it merely provides the necessary framework for conducting the statutory interpretation.

effect," Pet. for Cert. App. 24a. As such, this policy statement is a rule as that term is used in the APA, 5 U.S.C. § 551(4) (1982), governing FDA conduct. Center for Auto Safety v. NHTSA, 710 F.2d 842, 846 (D.C. Cir. 1983); Guardian Federal S&L Association v. Federal S&L Insurance Corp., 589 F.2d 658, 666-669 (D.C. Cir. 1978); Pickus v. United States Board of Parole, 507 F.2d 1007, 1112-1113 (D.C. Cir. 1974). It interprets the FDCA and sets forth FDA current policy regarding the unapproved use of approved drugs.

The government also now argues that the policy statement is "full of flexible terms that are not susceptible to judicial review," such as "widespread," "endangers the public health," and "whatever action is warranted." Pet. for Cert. 11-12. The government's claim that courts therefore would have to take over the day-to-day operations of the FDA to interpret these terms simply does not follow. First, these terms are no different from other terms which courts routinely interpret, and there is certainly nothing about them that would preclude their judicial interpretation and application. Second, and more to the point, judicial review does not call for courts to substitute their own judgment for that of an agency. Rather, the reviewing court's scrutiny of an agency decision is limited to whether the reasons relied upon by the agency make sense, see, e.g., Falkowski v. E.E.O.C., 719 F.2d 470, 481 n. 16 (D.C. Cir. 1983), and that is precisely the scope of the court of appeals' analysis here.

In addition to the FDA's policy statement, the case law supports judicial review of the FDA enforcement decision here. See, e.g., United States v. Evers, 643 F.2d 1043 (5th Cir., 1981); United States v. Beuthanasia D. Regular, supra, [1979 Transfer Binder] Food Drug Comm. L. Rep. (CCH) ¶ 38,265 (D. Neb. 1979); Hoffman-LaRoche, Inc. v. Weinberger, 425 F.Supp. 890

(D.D.C. 1975); American Public Health Association v. Veneman, 349 F.Supp. 1311 (D.D.C. 1972). Moreover, the express language of the statute indicates that Congress intended courts to review FDA activity. See, e.g., 5 U.S.C. § 332(a) (jurisdiction of courts over injunctive actions); id. § 346a(i) (judicial review of regulations which establish tolerances for pesticide chemicals); id. § 348(g) (judicial review for controversies over food additives); id. § 355(h) (judicial review of new drug orders); id. § 360g (judicial review of premarketing provisions).[14/] Finally, the legislative history indicates that Congress intended courts to review and to grant appropriate relief against "any act or omission on the part of the Department in the administration of the Act." S. Rep. No. 646, 74th Cong., 1st Sess. 1, 10 (1935).

In short, there is no "clear and convincing evidence" that Congress intended to preclude judicial review of the FDA's decision here. To the contrary, the evidence indicates that

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14/ The government asserts that this is a "paradigmatic case in which the governing statute provides no law to apply" since the statute "does not command the FDA to initiate investigative or enforcement activity." Pet. for Cert. 8-9. Assuming arguendo the FDCA is drafted solely in permissive terms, and it is not, permissive language alone is not "conclusive evidence of Congressional intent to preclude review. As a general matter, permissive statutory language only affects the scope of an agency's discretion; it does not constitute a license to undertake actions that are 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Local 12, American Federation of Government Employees v. Donovan, supra, 683 F.2d 511, 516 n.10 (D.C. Cir. 1983), quoting 5 U.S.C. § 706(a)(2). See also Hindros v. United States Civil Service Commission, 720 F.2d 278, 293 (3rd Cir. 1983); Fleming v. FTC, 670 F.2d 311, 316 n. 15 (D.C. Cir. 1982). Cf. Falkowski v. E.E.O.C., 719 F.2d 470, 480-481 n.16 (D.C. Cir. 1983) (the use of permissive rather than mandatory language in a policy statement that "representation by private counsel at federal expense may be provided to a federal employee" if certain preconditions are met does not preclude judicial review under the APA of an agency refusal to provide federal employee an attorney at government expense). In any event, the Act's prohibitions are expressed in mandatory terms. See, e.g., 21 U.S.C. § 333(a) (any person who violates § 331 "shall" be imprisoned or fined).

Congress intended the FDA's decisions to be subject to judicial review.

B. FDA's Enforcement Decision Is Arbitrary and Capricious.

Judicial review of agency decisions such as the FDA's requires courts to conduct a "searching and careful" review of the "whole record" to determine whether the agency has been "arbitrary and capricious." See 5 U.S.C. § 706(2)(A) (1976); FPC v. Transcontinental Gas Pipe Line Corp., 423 U.S. 326, 331 (1976) (per curiam); Citizens to Preserve Overton Park, Inc. v. Volpe, supra, 401 U.S. at 416. This entails reviewing the facts relied upon, the other facts in the record, the relevant factors considered, and the available alternatives considered. Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976).

The FDA's decision not to enforce the FDCA with regard to the unapproved use of drugs for lethal injection, in light of the complete administrative record and the agency's stated reasons for its inaction, is plainly arbitrary, capricious and without authority of law.

The Commissioner offered two reasons for refusing to enforce the FDCA with regard to the unapproved use of drugs for lethal injection even if FDA had jurisdiction. Pet. for Cert. App. 85a. First, he claimed that the case law in the area of using approved drugs for an unapproved purpose was "far from uniform." The court of appeals properly rejected this claim as nothing more than a variation of the meritless claim FDA had no jurisdiction. Pet. for Cert. App. 32a-33a.

Second, the Commissioner claimed that this unapproved use did not pose "a serious danger to the public health" since it was in accordance with "duly authorized statutory enactments in furtherance of proper state functions." Id. at 85a. This

assertion is simply remarkable in light of the uncontroverted affidavits of expert anesthesiologists which state unequivocally that the drugs used in lethal injection pose a substantial threat of torturous pain to persons being executed.[15/] The FDA's claim that the very real danger of a slow, agonizing death to hundreds of human beings is not a threat to the "public health" is particularly remarkable in light of its exercise of jurisdiction to insure the informed consent of prisoners taking part in clinical investigations. 21 CFR §§ 50.1 et seq. The arbitrariness and capriciousness of this "reason" are also demonstrated by the FDA exercise of its jurisdiction to insure that drugs used to kill animals have been proven safe and effective before they are utilized. United States v. Beuthanasia-D. Regular, supra, [1979 Transfer Binder] Food Drug Comm. L. Rep. (CCH) ¶ 38,265 (D. Neb. 1979). If drugs used to kill animals pose a serious threat to the public health, then certainly drugs used to kill human beings pose at least as great a threat.

In any event, the Commissioner's deference to state law here is unjustified -- the Supremacy Clause of the Constitution preempts any state law, like a lethal injection statute, that conflicts with federal law. Arkansas v. Kansas & Texas Coal Co., 183 U.S. 185, 189 (1901). This Court has concluded that the FDCA

15/ Since this case was decided below on a motion for summary judgment, respondents' factual allegations that lethal injection does not cause a "quick and painless" death and that it "poses a substantial threat of torturous and unnecessary pain to persons being executed" must be assumed to be true. Complaint, ¶ 18, App., infra, 7a. See Wolston v. Reader's Digest Association, Inc., 443 U.S. 157, 162 n.5 (1979); Bishop v. Wood, 426 U.S. 341, 347 n.11 (1976); United States v. Diebold, Inc., 369 U.S. 654, 655 (1962). Thus, the government's unsubstantial claim, made originally by Judge Scalia, that lethal injection actually will result in less pain than other forms of execution is irrelevant.

should be interpreted broadly, even if doing so "would result in far-reaching inroads upon customary control by local authorities of traditionally local activities." United States v. Sullivan, 332 U.S. 689, 693 (1948). Where Congress has chosen to exercise its power over interstate commerce in a particular case, as it has with the FDCA, then any state legislation which conflicts, even a state's exercise of its own police power, must give way. United States v. Sullivan, supra, 332 U.S. at 693; United States v. California, 297 U.S. 175, 185 (1935); McDermott v. Wisconsin, 228 U.S. 115, 131-132 (1913).

Therefore, the government's assertion that the "FDA was reasonable in deferring to the states' authority in this field," Pet. for Cert. 15, is meritless. This is merely a variation of the government's argument below that it does not have jurisdiction over state-licensed activity, an argument emphatically rejected by both the court of appeals and the dissent. Pet. for Cert. App. 9a-12a, 54a. In point of fact, the FDA itself recently rejected the argument it is now embracing. In 1978, the FDA concluded that it had authority under the FDCA to promulgate regulations protecting the interests of prisoners used as research subjects in clinical investigations submitted to the FDA. 43 Fed. Reg. 19,417 (1978). The proposed regulations are set forth in Subpart C of 21 CFR Part 50. During the notice and comment period, some comments challenged the FDA's authority to issue these regulations on the ground that they interfered with a state's authority to regulate its penal system. This is precisely the same argument the Commissioner relied upon to support his claim that he does not have the authority to regulate lethal injection drugs. Yet the FDA expressly rejected this argument in the context of drug investigations with state prisoners:

> One comment stated that the proposed regulations are an impermissible intrusion upon the rights of the States to manage their own prison systems. Two comments contended that FDA's regulations would violate a California law that permits prisoner research.
>
> FDA disagrees with these comments. These regulations impose no obligations on State prison authorities. They state that except in limited circumstances, the agency will not permit the use of prisoners in the clinical investigations it regulates under sections 505(i), 507(d), and 520(g) of the act or accept clinical investigations that involved prisoner subjects in support of applications for research or marketing permits for products regulated by FDA.

45 Fed. Reg. 36,388 (1980).

The government now contends that FDA's conduct was not arbitrary and capricious because the use of drugs for lethal injection does not constitute a "misbranding," and therefore the FDCA does not extend to this use.[16/] For the reasons set forth by the court of appeals, Pet. for Cert. App. 8a-16a, the agency has jurisdiction over drugs when used for this unapproved purpose. A state prison's use of drugs as a means of lethal injection results in these drugs being misbranded in the requisite statutory sense because the labels of these drugs do not contain either adequate directions for this unapproved use or adequate warning that this use may be dangerous or unsafe, to wit, directions which would prevent a slow, tortuous death. The FDA's overly restrictive reading of the Act ignores the repeated admonitions of this Court that the Act should be construed broadly. See, e.g., United States v. Rutherford, 442 U.S. 544, 552-54 (1979); United States v. Bacto-Unidisk, 394 U.S. 784, 798 (1969) ("Congress fully intended that the Act's coverage be as broad as its literal language indicates -- and equally clearly, broader than any strict medical definition might otherwise allow"); United States v. Sullivan, 332 U.S. 689, 693 (1948).[17/]

16/ The government has now abandoned its primary argument below, to wit, that FDA has no jurisdiction because the use of drugs by state prison officials falls within the practice-of-medicine exemption to the Act. Both the court of appeals and the dissent flatly rejected this argument. Pet. for Cert. App. 9a-12a, 54a.

17/ See also United States v. Sene X Eleemosynary Corp., 479 F.Supp. 970, 981 (S.D. Fla. 1979) ("The 'hold for sale' standard of section 301 has long been afforded a liberal reading"); United States v. 10 Cartons, Labeled in Part "Hoxsey," 152 F.Supp. 360, 364-365 (W.D. Pa. 1975) ("It is not the holding for sale in a technical legal sense which gives rise to the federal jurisdiction . . . but the fact that the channels of commerce have been used").

In sum, the FDA's decision was arbitrary and capricious.

DATED: May 25, 1984

Respectfully submitted,

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Counsel for Respondents

APPENDIX TO MEMORANDUM IN RESPONSE TO PETITION FOR A WRIT OF CERTIORARI

EDITOR'S NOTE

PAGES 1a thru 89a WERE POOR HARD COPY AT THE TIME OF FILMING. IF AND WHEN A BETTER COPY CAN BE OBTAINED, A NEW FICHE WILL BE ISSUED.

SUMMONS IN A CIVIL ACTION

United States District Court

FOR THE
District of Columbia

PARKER, J.

81- 2265

CIVIL ACTION FILE NO. _____

LARRY LEON CHANEY, ALTON FRANKS, CARL MORGAN, CHARLES W. DAVIS, ROBYN PARKS
Oklahoma State Penitentiary
P.O. Box 97
McAlester, Oklahoma 74501

DOYLE SKILLERN, JERRY JOE BIRD, HENRY MARTINEZ PORTER
Ellis Unit, Texas Department of Corrections
Route 6
Huntsville, Texas 77340

Plaintiffs

v.

RICHARD SCHWEIKER, as Secretary of Health and Human Services
200 Inowpendence Avenue, S.W.
Washington, D.C. 20201

Defendant

SUMMONS

To the above named Defendant : RICHARD SCHWEIKER

You are hereby summoned and required to serve upon David E. Kendall, Esq. and Stephen M. Kristovich, Esq., Williams & Connolly

plaintiff's attorney , whose address is 839 17th Street, N.W.
Washington, D.C. 20006

an answer to the complaint which is herewith served upon you, within 60 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint.

JAMES F. DAVEY
Clerk of Court

Deputy Clerk.

Date: 9/16/81

[Seal of Court]

NOTE.—This summons is issued pursuant to Rule 4 of the Federal Rules of Civil Procedure.

IN THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LARRY LEON CHANEY, ALTON FRANKS,
CARL MORGAN, CHARLES W. DAVIS,
ROBYN PARKS
Oklahoma State Penitentiary
P.O. Box 97
McAlester, Oklahoma 74501

DOYLE SKILLERN, JERRY JOE BIRD,
HENRY MARTINEZ PORTER
Ellis Unit
Texas Department of Corrections
Route 6
Huntsville, Texas 77340

Plaintiffs,

v.

RICHARD SCHWEIKER, as Secretary
of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendant.

PARKER, J.

81- 2265

Civil Action No. ____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I

INTRODUCTION

1. This action arises out of the failure of a federal agency to perform its statutory duty to take steps to prevent the States of Oklahoma, Texas, Idaho and New Mexico from using drugs to execute prisoners when there is no evidence that these drugs will be safe and effective (that is, quick and painless), for this radically new, non-therapeutic and non-medical use. On December 19, 1980, the plaintiffs petitioned the Secretary of the Department of Health and Human Services to take certain steps, including the holding of evidentiary hearings, to enforce the Federal Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 301 et seq., and to prevent this unapproved use of drugs. A copy of this petition

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is appended hereto as Exhibit A. Plaintiffs' petition alleged that there was in fact abundant evidence that the use of drugs for this purpose may actually result in the slow and painful deaths of condemned prisoners subjected to lethal injection. On July 7, 1981, the Secretary's agent, the Commissioner of the Food and Drug Administration, refused to take any of the action sought by plaintiffs' petition. A copy of the Commissioner's letter is appended hereto as Exhibit B. Plaintiffs therefore seek declaratory relief and an order compelling the Secretary of Health and Human Services to take the requisite steps to enforce the Act and prohibit this unapproved use of drugs.

II

PARTIES

A. PLAINTIFFS

2. Plaintiffs Larry Leon Chaney, Alton Franks, Carl Morgan, Charles W. Davis and Robyn Parks are inmates at the Oklahoma State Penitentiary and are currently under sentence of death by lethal injection.

3. Plaintiffs Doyle Skillern, Jerry Joe Bird and Henry Martinez Porter are inmates at the Ellis Unit of the Texas Department of Corrections and are currently under sentence of death by lethal injection.

B. DEFENDANT

4. Defendant Richard Schweiker is Secretary of the United States Department of Health and Human Services and is sued in his official capacity as such. As Secretary of Health and Human Services, defendant Schweiker has the duty and responsibility to enforce the FDC Act.

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III

JURISDICTION

5. Jurisdiction is vested in this Court pursuant to 28 U.S.C. § 1331(a) in that the matter in controversy arises under the laws of the United States and is brought against an officer of a United States agency in his official capacity.

6. Jurisdiction is also vested in this Court pursuant to the provisions of 28 U.S.C. § 1361, this being an action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to plaintiffs.

7. Pursuant to the provisions of Section 10 of the Administrative Procedure Act, 5 U.S.C. §§ 701-706, plaintiffs seek review of defendant Schweiker's denial of their petition. Through this denial, plaintiffs suffer legal wrong because of final agency action for which there is no other adequate remedy in a court, and they are adversely affected and aggrieved by agency action within the meaning of a relevant statute.

8. Pursuant to the provision of 28 U.S.C. § 2201, plaintiffs seek a declaration of defendant Schweiker's obligations under the FDC Act with respect to the regulation of drugs used by the States in lethal injection executions and of plaintiffs' rights to be free from injection with drugs which are not safe and effective for their intended purpose as required by the FDC Act.

IV

STATEMENT OF CLAIM

9. Since 1977, four States -- Oklahoma, Texas, Idaho and New Mexico -- have enacted statutes mandating the use of drugs for a radically new purpose: the execution of human beings by lethal injection. Over 180 prisoners are now under sentences of death imposed pursuant to these statutes.

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10. Oklahoma became the first State to adopt a lethal injection statute in 1977. The Oklahoma statute describes that State's method of execution by a lethal dose of drugs as follows:

> "The punishment of death must be inflicted by continuous, intravenous administration of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician according to accepted standards of medical practice."

Okla. Stat. Tit. 22, § 1014A. According to Oklahoma Department of Corrections Policy and Procedures Memorandum Number OP-060301 (Revised) issued July 21, 1981, the ultrashort-acting barbiturate to be used is sodium thiopental, while the chemical paralytic agent to be used is either tubocurarine, succinylcholine chloride or potassium chloride.

11. Abbott Laboratories, of North Chicago, Illinois, manufactures sodium thiopental. Eli Lilly and Company, of Indianapolis, Indiana, manufactures tubocurarine. Squibb & Sons, Inc., of Princeton, New Jersey, and Burroughs Wellcome Co., of Research Triangle Park, North Carolina, manufacture succinylcholine chloride. Invenex Laboratories, of Orlando, Florida, manufactures potassium chloride. These drugs are manufactured for distribution and sale in interstate commerce.

12. The Texas lethal injection statute, also adopted in 1977, provides that death shall be caused "by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death." Tex. Code Crim. Proc. Ann. Art. 43.14. According to the Texas Department of Corrections Procedures for the Execution of Inmates Sentenced to Death, the drug to be used in execution is sodium thiopental.

13. The Idaho statute, enacted in 1978, provides as follows:

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> "The punishment of death must be inflicted by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death until the defendant is dead. The director of the department of corrections shall determine the substance or substances to be used and the procedures to be used in any execution."

Idaho Code § 19-2716. The Idaho Department of Corrections Death Penalty Procedures do not specify what the lethal drug will be.

14. The New Mexico execution statute, enacted in 1979, is similar to Oklahoma's statute:

> "The manner of inflicting punishment of death shall be by administration of a continuous, intravenous injection of a lethal quantity of an ultra-short-acting barbiturate in combination with a chemical paralytic agent."

N.M. Stat. § 31-14-11. There are no New Mexico Department of Corrections regulations designating the drugs to be used in an execution.

15. The FDC Act prohibits the interstate distribution of any "new drug" (including any previously known drug that is being used for a new purpose) unless the Secretary of Health and Human Services has approved an application supported by substantial evidence of the drug's safety and effectiveness for its specified purpose. 21 U.S.C. § 355(a). The term "new drug" is defined by § 201(p)(1) of the FDC Act, 21 U.S.C. § 321(p)(1), to mean

> "Any drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . . "

Under the FDC Act, general recognition of a drug's safety and effectiveness requires an "expert consensus" founded upon "substantial evidence," which the Act defines as:

> "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the

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> effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have. . . ."

21 U.S.C. § 355(d).

16. The Secretary, and his agent, the Commissioner of the Food and Drug Administration, have the statutory duty and responsibility of enforcing the FDC Act by, inter alia, promulgating regulations and holding hearings, 21 U.S.C. § 371, by conducting examinations and investigations, 21 U.S.C. § 372, by requiring record-keeping, 21 U.S.C. § 373, by making inspections, 21 U.S.C. § 374, and by issuing public reports, 21 U.S.C. § 375.

17. There is no evidence and no consensus in the scientific community that injection of the prescribed drugs will result in the quick and painless death of the condemned prisoner. Indeed, the only medical experts who have scientifically reviewed the humaneness and effectiveness of lethal injection, the British Association of Anesthetists and the British Medical Association, concluded that it did not present an acceptable alternative to traditional means of execution because quick and painless death was unlikely to result.

18. There is abundant evidence that the lethal injection authorized by the four State statutes is not a "safe and effective" (that is, quick and painless) means of executing human beings and that its use poses a substantial threat of torturous and unnecessary pain to persons being executed.

19. The American Medical Association and the professional medical societies of each of the four States with lethal injection statutes have all passed or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a lethal injection execution other than to make a determination or certification of death.

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20. In both administrative and judicial proceedings, the Secretary and his agents have stringently enforced the FDC Act as applied to the regulation of drugs used by veterinarians to kill domestic animals, taking the position that such chemicals were "drugs" under the FDC Act for which new drug applications had to be filed demonstrating satisfaction of the FDC Act's requirements of safety and effectiveness.

21. The Secretary of Health and Human Services and his agents have not issued approvals for drugs to be used for the lethal injection of a human being.

22. Lethal injection involves the untested and unapproved use of drugs manufactured, distributed, and sold in interstate commerce to kill human beings and therefore violates the FDC Act.

23. On December 19, 1980, plaintiffs petitioned the Secretary of Health and Human Services pursuant to 21 C.F.R. § 10.30 to take certain steps to enforce the Act and to prevent the unapproved use of drugs as a means of lethal injection. See Exhibit A, attached hereto.

24. Plaintiffs requested an evidentiary hearing on any controlling issue of fact raised by their petition. Exhibit A, at Page Nineteen.

25. Plaintiffs' petition contained a detailed recitation of the known evidence concerning lethal injection, which indicates that it is likely to cause slow and painful death in many cases. Plaintiffs appended to their petition three affidavits of leading medical and scientific experts (including the former president of the Florida Medical Association, and the Director of Anesthesiology at Boston's Peter Bent Brigham Hospital), which aver that there is no published scientific data or

information respecting the safety and efficacy of lethal injection, that there are risks that intense pain may be caused in the administration of lethal drugs, and that there is a high likelihood that lethal injection may not produce speedy death.

26. Despite the Secretary's obligation under the FDC Act to prevent the harmful use of an approved drug in an unapproved manner, on July 7, 1981, the Secretary's agent, the Commissioner of the Food and Drug Administration, denied plaintiffs' petition without affording them an evidentiary hearing and refused to take any of the action sought by plaintiffs' petition. See Exhibit B, attached hereto.

27. The Commissioner's action in summarily rejecting plaintiffs' petition without consideration of any of the relevant evidence was unlawfully arbitrary, capricious, and an abuse of discretion. It was in disregard of the statute and failed to observe procedure required by law. It was unsupported by substantial evidence, and unwarranted by the facts to the extent that the facts are subject to trial de novo by this Court. It constitutes a plain failure to perform a legal duty owed to the plaintiffs. Plaintiffs and defendant are in actual controversy as to the interpretation of the FDC Act and defendant's duties under that Act in relation to the regulation of new drugs to be used for the purpose of killing persons by lethal injection.

28. As set forth above, the actions of the defendant, except for the intervention of this Court and the granting of the relief prayed for herein, will cause plaintiffs irreparable injury for which they have no adequate remedy at law.

V

PRAYER

WHEREFORE, plaintiffs pray for a judgment declaring that the use of drugs by state departments of corrections for lethal

injection presents a substantial question whether this practice violates the FDC Act and presents disputed factual issues that should be resolved in the first instance by the Food and Drug Administration. Plaintiffs also pray for an order requiring the Secretary of Health and Human Services to immediately hold evidentiary hearings, pursuant to the FDC Act, at which hearings plaintiffs may present relevant scientific and medical evidence, and to make detailed factual findings as to whether there is substantial evidence and an expert consensus that lethal injection, as administered in the States of Texas, Oklahoma, Idaho, and New Mexico is not violative of the FDC Act. The Secretary should be further required to consider whether any or all of the following steps may be necessary to prevent violations of the FDC Act:

(i) Affixation of a boxed warning to the labels of the drugs specified for use in a lethal injection execution in Oklahoma, Texas, Idaho and New Mexico that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

(ii) Distribution to the manufacturers of these drugs and to the departments of corrections in Oklahoma, Texas, Idaho and New Mexico of notices advising that the drugs specified in those States' execution statutes or prison policies for use in an execution are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

(iii) Placement in the Drug Bulletin of an article advising that the drugs specified for use in a lethal injection by statutes or prison policies in Oklahoma, Texas, Idaho and New Mexico are not approved for use as a means of execution, are not

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considered safe and effective as a means of execution, and should not be used as a means of execution;

(iv) Adoption of a policy and procedure for the seizure and condemnation in prisons or State departments of corrections of drugs which are destined or held for use as a means of execution;

(v) Recommendation of the prosecution of manufacturers, wholesalers, retailers and pharmacists who knowingly sell drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess or use drugs for the unapproved use of lethal injections.

Respectfully submitted,

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Counsel for Plaintiffs

Date: September 16, 1981

11a

EXHIBIT A

12a

December 19, 1980

The Honorable Patricia Roberts Harris
Secretary, Department of Health and
Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Harris:

During the last three years, four states -- Texas, Oklahoma, Idaho and New Mexico -- have enacted statutes mandating the use of specified drugs for a radically new purpose: the execution of human beings by "lethal injection." Prisons in these four states currently house 166 of the 691 persons under sentence of death in the United States. At least six other states -- Florida, Tennessee, Nevada, South Carolina, Washington, and Kansas, which have a total of 186 death row inmates -- have also seriously considered adopting some method of lethal injection.

Although the supporters of this new method of execution have advanced several pragmatic reasons for its adoption (for example, its inexpensive administrability, 1/ its greater

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1/ At the time Okahoma adopted its lethal injection statute, necessary repairs to the electric chair would have cost $62,000. An alternative option to build a gas chamber would have cost more than $200,000. The Oklahoma legislators were informed that death by injection would cost only $10 to $15 "per event." P. Malone, "Death Row and the Medical Model," Hastings Center Report p. 5 (October 1979).

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palatability to those who witness executions, 2/ and the possibility that it will increase the incidence of executions in this country 3/), they usually accompany these practical reasons with a totally unsubstantiated "humanitarian" argument of particular relevance to you in light of your responsibilities under the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. §§ 301 et seq. -- i.e., that the injection of drugs is a more humane and less painful means of executing people than the traditional methods 4/ of electrocution, gas, hanging and shooting. In point of fact, lethal injection involves the use, by non-doctors, of drugs in an entirely

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2/ This rationale has become increasingly important recently as the number of potential witnesses to executions has increased. It is no coincidence, for example, that the Texas legislature passed its lethal injection statute shortly after a court held that executions in that state could be televised. Prior to passage of that statute, the laws of Texas mandated death by electrocution, which results in a visibly roasting skin, bulging eyeballs, bleeding nose and bursting bowels.

The effect on witnesses of a method of execution, of course, must be distinguished from its effect on the person being executed. For example, proponents of electrocution have long advanced the theory that, despite its gruesome aspect to witnesses, electrocution's effect on its victim is the instantaneous destruction of the nervous system, thereby precluding pain or any other sensation whatsoever.

3/ Those advocates of lethal injection who are also strong advocates of capital punishment argue that since this method of execution is perceived by the public as more palatable, its adoption will decrease opposition to the death penalty, encourage judges and juries to sentence more people to death and discourage executive officials from commuting or failing quickly to carry out those sentences.

4/ Currently, the following means of execution are in force in the fifty states, Puerto Rico and the District of Columbia: electrocution (18); gas (10); hanging (5); lethal injection (4); shooting (1). Fourteen of these fifty-two jurisdictions do not have a death penalty.

new, non-therapeutic and non-medical fashion for which their safety and effectiveness have never been tested. In addition, there is strong evidence to believe that their use may actually result in agonizingly slow and painful deaths that are far more barbaric than those caused by the more traditional means of execution. In any event, there is absolutely no evidence, let alone a consensus in the scientific community, that the use of these drugs will result in the quick and painless death that their advocates claim. 5/ Furthermore, their manufacturers 6/ have never applied to you for approval of this use of these drugs, nor, of course, have you granted such approval.

In a directly analoguous case initiated by the Food and Drug Administration ("FDA"), a federal court in Nebraska last year ruled that drugs used by veterinarians to kill domestic animals were drugs under the Act and that their introduction into interstate commerce violated the Act since "new drug" applications had not been filed demonstrating that those drugs satisfy the Act's requirements of safety and effectiveness. United States v. Beuthanasia D Regular, CCH Food Drug Cosmetic Law Reports ¶ 38,265 (D. Neb. 1979). According to FDA Policy Guide No. 7125.17, September 15, 1977, products intended for animal euthanasia are drugs because they are intended to affect the function of the body by inducing death. The court expressly noted that relevant criteria in assessing the safety and effectiveness of such drugs included, inter alia, (1) the drug's ability to cause death without pain and discomfort; (2) the time required to produce loss of consciousness; (3) the time required to produce death; (4) the reliability of the drug to obtain consistently effective results. Id. at 39,129.

5/ Indeed, the only medical experts who have considered the humaneness and effectiveness of "lethal injection" drugs, the British Association of Anesthetists, concluded that such drugs do not present a viable alternative to traditional means of execution. See p. 9, n.9, infra.

6/ Abbott Laboratories manufactures sodium thiopental. Eli Lilly and Company manufactures tubocurarine. Squibb & Sons, Inc. and Burroughs Wellcome Co. manufacture succinylcholine chloride. Invenex Laboratories manufactures potassium chloride. Physicians Desk Reference (34th Ed. 1980).

By way of this petition, therefore, the undersigned counsel, on behalf of Larry Leon Chaney, an inmate at the Oklahoma State Penitentiary, who is currently under sentence of death by lethal injection, and Doyle Skillern, an inmate at the Ellis Unit of the Texas Department of Corrections, who is currently under sentence of death by lethal injection, request that you take the steps delineated below to enforce the Act against the unapproved use of drugs for this unprecedented purpose of "lethal injection."

The Lethal Injection Statutes

Oklahoma became the first state to adopt a lethal injection statute in 1977. The Oklahoma statute describes that state's method of execution by a lethal dose of drugs as follows:

> "The punishment of death must be inflicted by continuous, intravenous administration of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician according to accepted standards of medical practice."

Okla. Stat. tit. 22, § 1014A. According to Oklahoma Department of Corrections Policy and Procedures Memorandum Number OP-090901 issued April 12, 1978, the ultrashort-acting barbiturate to be used is sodium thiopental, while the chemical paralytic agent to be used is either tubocurarine, succinylcholine chloride or potassium chloride.

The Texas lethal injection statute, also adopted in 1977, provides that death shall be caused "by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death." Tex. Code Crim. Proc. Ann. art. 43.14. According to the Texas Department of Corrections Procedures for the Execution of Inmates Sentenced to Death, the drug to be used in execution is sodium thiopental.

The Idaho statute, enacted in 1978, provides as follows:

> "The punishment of death must be inflicted by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death until the defendant is dead.

> The director of the department of corrections shall determine the substance or substances to be used and the procedures to be used in any execution."

Idaho Code § 19-2716. The Idaho Department of Corrections Death Penalty Procedures do not specify what the lethal drug will be.

The New Mexico execution statute, enacted in 1979, is similar to Oklahoma's statute:

> "The manner of inflicting punishment of death shall be by administration of a continuous, intravenous injection of a lethal quantity of an ultra-short-acting barbiturate in combination with a chemical paralytic agent."

N.M. Stat. § 31-14-11. There are no New Mexico Department of Corrections policy or procedure statements designating the drugs to be used in an execution.

The Department of Health and Human Services Has the Authority and the Responsibility To Prevent the Use of Approved Drugs for the Unapproved Use of Lethal Injection

Lethal injection, the untested and unapproved use of drugs to kill people, violates the procedures of and the policies underlying the Federal Food, Drug and Cosmetic Act:

> "When a manufacturer or anyone in the chain of distribution suggests to a patient that an approved drug may properly be used for unapproved uses for which it is neither labelled nor publicly advertised, that action constitutes a violation of the act and is punishable accordingly as a misbranding of the drug. [Under Food and Drug Administration policy] a . . . person who ships or requests shipment of a prescription new drug in interstate commerce with the intent of applying it to an unapproved use . . . must first file with the Food and Drug Administration an investigational new drug plan as set out in 21 CFR, § 312.1."

United States v. Evers, 453 F. Supp. 1141, 1148 (M.D. Ala. 1978); see also United States v. An Article of Drug * * * Diso-Tate, Etc., H. Ray Evers, and Meadowbrook Hospital, CCH Food Drug Cosmetic Law Reports ¶ 38,086 (E.D. La. 1976) (defendant lay person enjoined from using approved drug in unapproved fashion in direct contradiction to label). Furthermore, the FDA has emphatically stated that it will do all in its power to prevent the unapproved and dangerous use of approved drugs:

> "Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. Several alternative courses of action are available to the Food and Drug Administration under these circumstances, depending upon the specific facts of each case. These actions include: Requiring a change in the labeling to warn against or to approve the unapproved use, seeking substantial evidence to substantiate the use, restricting the channel of distribution, and even withdrawing approval of the drug and removing it from the market in extreme cases. When necessary, the Food and Drug Administration will not hesitate to take whatever action of this nature may be required to bring possible harmful use of an approved drug under control.
>
> • • •
>
> Thus, where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or to the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly."

37 Fed. Reg. 16504 (1972) (emphasis added.) The Act was held to apply to drugs used to kill animals last year. Certainly the Act applies with no less stringency for drugs used to kill human beings. 7/

7/ The Federal Food, Drug and Cosmetic Act prohibits the interstate distribution of any "new drug" (including any previously known drug that is being used for a new purpose) unless the Secretary of Health and Human Services has approved an application supported by substantial evidence of the drug's safety and effectiveness for its specified purpose. 21 U.S.C. § 355(a).

The term "new drug" is defined by § 201(p)(1) of the Act, 21 U.S.C. § 321(p)(1), to mean

> "Any drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . ."

Although the Act does not define what constitutes general recognition of a drug's safety and effectiveness, the Supreme Court has interpreted this requirement to mean an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in the Act. United States v. Rutherford, 442 U.S. 544, 549-50 n.7 (1979). The Act defines "substantial evidence" as follows:

> "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have. . . ."

21 U.S.C. § 355(d).

(Footnote continued)

There is Strong Evidence That the Lethal Injection of Drugs Is Not A "Safe and Effective" Means of Executing People and That Its Use Poses A Substantial Threat of Torturous Pain to Persons Being Executed

According to Dr. Richard S. Hodes and Dr. Leroy Vandam, both of whom are accomplished anesthesiologists familiar with the drugs specified for use in a lethal injection as well as with the "intravenous" injection procedure mandated in all four lethal injection statutes and their interpreting regulations, 8/ those

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(Footnote continued)

7/ The affidavits submitted by Drs. Vandam, Hodes and Casscells as part of this petition convincingly demonstrate that there is by no means an "expert consensus" founded upon "substantial evidence" consisting of "adequate and well-controlled investigations," including "clinical investigations," that the drugs to be used to execute people will have the effect they purport or are represented to have, to wit, that they will produce loss of consciousness and death quickly and without pain and discomfort. These experts are not aware of any published scientific data or information which in any respect addresses the use of these drugs as a means of execution, much less establishes their effectiveness. Nor are these experts aware of any adequate and well-controlled investigations establishing the effectiveness of these drugs for a lethal injection.

Thus, to the extent that the manufacturers or anyone in the chain of distribution of sodium thiopental, tubocurarine, succinylcholine chloride and potassium chloride promote the use of these drugs for the unapproved use of lethal injections, a violation of the Act occurs and the Department of Health and Human Services should take appropriate action to end such violations.

8/ Dr. Hodes is former president of the Florida Medical Association. Dr. Vandam is Professor of Anesthesia, Emeritus, at Harvard Medical School, Anesthesiologist to Boston's Peter Bent Brigham Hospital and Director of Anesthesiology at Boston's Hospital at Parker Hill, a hospital run by the Harvard Community Health Plan. Curricula vitae for both Dr. Hodes and Dr. Vandam are attached to their affidavits.

drugs and that procedure may well not produce a quick, painless death. In particular, intravenous injection of drugs is a delicate and skilled operation which requires professional expertise. Even when performed by an expert, the process of intravenous injection and the determination of the dosage to be injected are always subject to substantial technical difficulty, which may result in the infliction on the recipient of severe physical and mental pain. For these reasons, the British Association of Anesthetists and the British Medical Association disapproved of lethal injections in reports to the Royal Commission on Capital Punishment, which Commission, in turn, recommended to Parliament that it not adopt lethal injection as a means of execution. 9/

There are at least four separate reasons why the intravenous injection of drugs is an unsafe, ineffective and inhumane means of executing people even when administered by expert medical practitioners:

9/ According to the Report of the Royal Commission on Capital Punishment presented to the English Parliment in 1953 (Exhibit 1), the British Association of Anesthetists rejected lethal injection as impracticable for three reasons:

> "First, it is impossible to give an intravenous injection to anyone with certain physical abnormalities. Secondly, it is never easy to give one except with the cooperation of the subject. Thirdly, the operation demands professional skill, which the medical profession would be unwilling to use for such purpose."

Report, Royal Commission on Capital Punishment 1949-1953, p. 258 (September 1953). The British Medical Association also rejected lethal injection: "the practical difficulties encountered in many cases when injection into a vein is attempted are such as to render the method quite unsuitable for the purpose of execution." Id. The Report also notes that the prison medical officers interviewed by the Commission were of the opinion that lethal injection was no more humane than hanging. Id. at 257.

First, it is extremely difficult, if not impossible, to give intravenous injections to persons with certain physical conditions and abnormalities. Specifically, it is difficult to locate and enter veins in the obese, in persons with heavily pigmented skin, in drug addicts where veins may be thrombosed as the result of prior drug injections, in the elderly with fragile veins, and in persons with a history of diabetes, uremia and other conditions. Given the high percentage of black and other minority inmates on death row, 10/ and the disproportionately high incidence in minorities of these physical conditions and abnormalties associated

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10/ Three hundred twenty-two (322) of the 691 prisoners currently on death row in this country are black or members of another minority group. The President's Commission on Law Enforcement and Administration of Justice concluded that "there is evidence that the imposition of the death sentence and the exercise of dispensing power by the courts and the executive follow discriminatory patterns. The death sentence is disproportionately imposed and carried out on the poor, the Negro, and the members of unpopular groups." The Challenge of Crime in a Free Society, a Report by the President's Commission on Law Enforcement and Administration of Justice 143 (1967).

Less than two months ago, the Supreme Judicial Court of Massachusetts in District Attorney v. Watson, ___ Mass. ___, 411 N.E.2d 1274 (October 28, 1980), ruled that the death penalty violates the prohibition against cruel or unusual punishment contained in article 26 of that State's Declaration of Rights for two reasons: it is unacceptably cruel under contemporary standards of decency and it is administered with unconstitutional arbitrariness and racial discrimination. The court cited data from 1972 through 1977 to show that the death penalty was arbitrarily and discriminatorily administered against blacks:

> "In Florida, of 286 blacks who had killed whites, forty-eight (16.8%) were sentenced to death; of 111 whites who killed blacks, none were sentenced

(Footnote continued)

with difficult intravenous injection, 11/ the difficulty of intravenous injection would be a problem which would present itself with substantial frequency in administering lethal injections.

In addition, the average person, when faced with the typically fearful prospect of an intravenous injection, experiences the constriction of veins as a result of sympathetic nervous activity, i.e., the release of adrenalin. Given the uniquely horrible consequences of a lethal injection of drugs, it is highly probable that in the moments before his or her scheduled execution a death row inmate's veins would become constricted, thereby increasing

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(Footnote continued)

10/ to death. In Georgia, of 258 blacks who killed whites, thirty-seven (14.3%) were sentenced to death; of seventy-one whites who killed blacks, two (2.8%) were sentenced to death. In Texas, of 344 blacks who killed whites, twenty-seven (7.8%) were sentenced to death; of 143 whites who killed blacks, none were sentenced to death. . . .

> "[In] Ohio . . . of 173 black persons who killed white persons, thirty-seven of them (21.4%) were sentenced to death. Of forty-seven whites who killed blacks, none were sentenced to death."

411 N.E.2d at 1285-86. (emphasis in original).

11/ Obviously, the incidence of heavy skin pigmentation is much higher among blacks and other minorities. However, the same is true of many of the other physical characteristics associated with difficulty in administering an intravenous injection. For example, minorities are significantly more likely to suffer from diabetes, and twice as likely to die from that malady, than whites. Similarly, the incidence of abuse of intravenously injected drugs is much higher among minorities than among whites. U.S. Department of Health, Education and Welfare, Health Status of Minorities and Low-Income Groups, at 106, 125-26, 180-81 (1979).

the difficulty of performing an intravenous injection. Furthermore, an intravenous injection is considerably more difficult and unreliable in a resisting individual, a likely possibility given the circumstances of a lethal injection.

Under any of the circumstances discussed above, intravenous injection might result in painfully repeated but very possibly unsuccessful efforts to "find" a vein, or in the injection of the drug into either the tissues surrounding the vein or into an artery, the excruciating consequences of which are discussed below.

Second, insertion of a needle into a vein is always painful, even if a local anesthetic is first used. Repeated attempts at finding a vein cause additional pain and result in the escape of blood into the surrounding tissues, causing painful swelling and occlusion of other veins.

Third, even if the needle appears to be within a vein, the drug nevertheless might escape into the surrounding tissues upon injection, causing severe pain and swelling. This would be especially likely to occur in persons with flat veins which make it impossible to prevent the needle, which has pierced one wall of the vein, from going through the opposite wall as well. Sodium thiopental is a highly alkaline solution (ph 11.5) which causes local thrombosis of the vein in some people. Given the nature of the drugs used in lethal injections, the result of this subcutaneous administration would be highly painful. For example, if sodium thiopental accidently enters tissue, painful neuritis occurs if a nerve is adjacent. The same results occur with potassium chloride and acidic solutions such as succinylcholine and tubocurarine.

Because of the difficulty in performing an intravenous injection, it is also very possible to inject the drug mistakenly into an artery causing the artery to constrict and the surrounding tissue to die, often with extensive gangrene, and always with excruciating pain to the recipient. As the result of the drug escaping into the surrounding tissues or entering an artery, moreover, the injected drug would fail to produce its intended result.

Fourth, determining the proper dosage of drugs to be used in a lethal injection would be an extremely difficult task. Response to a set dosage varies from person to person depending

upon several factors including age, body mass, physical condition and current as well as prior use of other drugs. It is likely, for example, that a drug addict or alcoholic would need more than a normal dosage. Furthermore, some people are born with genetic responses to drugs which might also influence dosage.

When used for such therapeutic purposes as anesthesia, thiopental, tubocurarine and the other lethal injection drugs are given intermittently in measured amounts until the desired effect is achieved. Even in a well-controlled hospital setting, however, it is not very unusual for a patient to experience pain or to recall operative events when presumably asleep. In the tension-packed setting of an execution, the results could be excruciating. If in administering death by injection of drugs an insufficient amount of thiopental were administered, for example, followed by tubocurarine or some other paralytic agent, the recipient could awaken paralyzed and unable to breathe, with the result that he or she would die an excruciatingly slow death in conscious physical and mental agony. This might also occur if the thiopental escaped into the surrounding tissue upon injection or were accidentally injected into an artery.

Thus, the successful administration of a painless lethal injection and the determination of the correct dosage of drugs to be used would be very difficult even for the most highly trained and experienced of physicians. In practice, however, the risks of improper administration or determination of dosage in the context of lethal injections would be substantially greater because highly trained expert physicians and other health professionals will not -- indeed, legally and ethically cannot -- participate in such activity.

Participation of a physician in an execution by lethal injection, be it through the ordering of the drugs, the preparation of the dosage, the actual administration of the injection or the supervision of others in carrying out these tasks, would be a violation of the physicians' Hippocratic Oath, the ethical guide of the medical profession for 2500 years, which provides:

> "To please no one will I prescribe a deadly drug, nor give advice which may cause his death." 12/

12/ Dorland's Illustrated Medical Dictionary (24th Ed. 1965).

The American Medical Association ("AMA") and the professional medical societies of each of the four states with lethal injection statutes have all passed or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a legally authorized execution other than to make a determination or certification of death. 13/

13/ On July 22, 1980, the American Medical Association's governing body, the House of Delegates, adopted the following recommendation of the AMA Judicial Council:

> "A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution."

The Oklahoma Medical Association is a "unified" professional society, which means that all members of the Oklahoma Medical Association are also members of the AMA and must therefore follow its guidelines.

On August 2, 1980, the Council of the New Mexico Medical Society endorsed the recently adopted AMA position.

Similarly, on July 26, 1980, the Idaho Medical Association's House of Delegates adopted a resolution advising its members not to participate in executions by administration of a lethal substance because "it is contrary to medical ethics for a physician to take a human life under any circumstances." The Idaho Medical Association formally stated that "a physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

On May 11, 1977, immediately following passage of the Texas lethal injection statute, the Texas Medical Association Board of Councilors declared that a physician, by virtue of the Hippocratic Oath, cannot take a life under any circumstances. The Board unanimously agreed to adopt the following opinion:

(Footnote continued)

The condemnation by the various medical societies of physicians' medical participation in the preparation, administration or supervision of a lethal injection is consistent with the views articulated by Dr. William J. Curran of Harvard Medical School and Dr. Ward Casscells, co-authors of "The Ethics of Medical Participation in Capital Punishment by Intravenous Drug Injection" published in the January 24, 1980 edition of The New

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(Footnote continued)

13/ "A physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

This position was reaffirmed by the Board of Councilors in May, 1980.

Similarly, on June 20, 1980, the Board of Trustees of the American Psychiatric Association ("APA") approved the following statement:

> "The physician's serving the state as an executioner, either directly or indirectly, is a perversion of medical ethics and of his or her role as healer and comforter. "APA therefore strongly opposes any participation by psychiatrists in capital punishment, that is, in activities leading directly or indirectly to the death of a condemned person as a legitimate medical procedure."

137 Am.J. Pschiatry 1487 (November 1980).

It is likely that many if not most physicans would refuse to be present at a lethal injection even for the sole purpose of certifying death. According to Dr. Ward Casscells and Dr. William Curran, it is ethically improper for a physician to be present and performing a monitoring role at a lethal injection:

(Footnote continued)

England Journal of Medicine. In this article, Dr. Curran and Dr. Casscells forcefully express the view that a physician's preparation, administration or supervision of a lethal injection is a violation of ethical principles of the medical profession and a

> "perversion of biomedical knowledge and skill for a nonmedical purpose. It would, in our judgment, violate the medical practice act of any American jurisdiction."

(Attachment 1 to Dr. Casscell's Affidavit at p. 4.)

In addition to being contrary to the traditional Hippocratic Oath, a physician's participation in a lethal injection would be in violation of the World Medical Association's Declaration of Geneva, the modern version of the oath, which provides "even under threat, I will not use my medical knowledge contrary to the laws of humanity." This Declaration was adopted in 1948 in response to the atrocities committed by medical personnel in Nazi Germany. The defense of Nazi physicians that they were following orders was rejected as a violation of the moral imperative

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(Footnote continued)

13/ "It is similar to the physician who examines the prisoner intermittently during torture or prolonged interrogation and pronounces him physically fit to continue his ordeal. The 'continuous intravenous injection' ends only when the monitoring physician pronounces the condemned prisoner dead. The physician then becomes the instrument, the order, to stop the lethal action itself. There is no other way to describe this physician's role but as that of an active participant, a key human participant, in the execution."

See "The Ethics of Medical Participation In Capital Punishment By Intravenous Injection," The New England Journal of Medicine 226,229 (Jan. 24, 1980), Attachment 1 to Dr. Casscell's Affidavit at p. 4.

to refuse to kill or to harm the prisoners or to take part in atrocities in any way. 14/

The licensing laws and ethical standards for nurses and medical technicians would also prevent them from carrying out a lethal injection. This is so not only because all health professionals adhere to their own versions of the Hippocratic Oath, but also because such personnel do not have the authority to prepare or administer a drug dosage independent of a physician's specific order or valid standing orders, which orders, of course, could not ethically or legally be forthcoming from doctors. Furthermore, such personnel would be even less experienced than physicians in carrying out drug injections since they would be less likely to have worked with laboratory animals.

The ethical principles which prohibit physicans from participating in a lethal injection would also make it improper for physicians to train any other person to perform lethal injections, assuming even that physicians possessed the skills and knowledge to provide the training. Of course, physicians are not trained to prepare lethal "medications" for human administration, and few, if any, physicians would have experience in administering poison or medication overdoses continuously to the point of death.

14/ Nazi Germany has not been the only time and place where physicians have disregarded their moral obligation and turned their knowledge of the healing arts to torture and death. Other chilling examples have been described by Solzhenitsyn in Stalinist Russia and by Amnesty International in Chile, Iran, Paraguay, Portugal and Argentina. See "The Ethics of Medical Participation in Capital Punishment By Intravenous Injection," The New England Journal of Medicine 226, 227-28 (Jan. 24, 1980), Attachment 1 to Dr. Cassell's Affidavit at pp. 2-3. These examples are clearly extreme, but they explain why the American medical societies have unanimously rejected physicians' participation in lethal injections as the state's executioner.

The Department of Health and Human Services Should Exercise Its Statutory Authority and Responsibility To Enforce the Act Against the Unapproved Use of Lethal Injection Drugs

To date, no person has been put to death by an injection of a lethal dose of drugs. The day is fast approaching, however, when the final appeals of prisoners on death row in Texas, Oklahoma, Idaho or New Mexico will be exhausted. Under an unsubstantiated medical veneer of humanity and decency, the first execution by means of a drug poses a real threat of leading to society's widespread but misguided acceptance of lethal injection as a cheap and deceptively palatable way of performing executions. Before this occurs, the time should be taken by your Department, pursuant to its statutory responsibility, to step back and analyze what is in fact taking place: the use of untested drugs to kill people, administered not by trained physicians or other health professionals in their practice of medicine, but by untrained, nonprofessional personnel.

Therefore, pursuant to the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, on behalf of Larry Leon Chaney and Doyle Skillern, death row prisoners in Oklahoma and Texas who are currently under sentences of death by lethal injection, we hereby request by means of this petition filed pursuant to 21 C.F.R. § 10.30 that you take the following steps:

1. Affix a boxed warning to the labels of the drugs specified for use in a lethal injection by statutes or prison policies in Texas, Oklahoma, Idaho and New Mexico that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

2. Prepare and send to the manufacturers of the drugs and to prisons and departments of corrections in Texas, Oklahoma, Idaho and New Mexico (see Exhibit 2) notices advising that the drugs specified in those states' execution statutes or prison policies for use in an execution as well as any other drug or drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

3. Place in the Drug Bulletin an article advising that the drugs specified for use in a lethal injection by statutes or prison policies in Texas, Oklahoma, Idaho and New Mexico are not

approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not to be used as a means of execution;

4. Adopt a policy and procedure for the seizure and condemnation from prisons or state departments of corrections of drugs which are destined or held for use as a means of execution;

5. Recommend the prosecution of manufacturers, wholesalers, retailers and pharmacists who knowingly sell drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess or use drugs for the unapproved use of lethal injections.

If after reviewing this petition you would like additional information or clarification of the matters presented, we would be happy to meet with you to discuss the issues raised by this petition. Furthermore, petitioners request a hearing on any controlling issue of fact raised by this petition.

We look forward to your prompt response to this petition. 15/

Sincerely,

Stephen M. Kristovich

David E. Kendall
Stephen M. Kristovich

WILLIAMS & CONNOLLY
Hill Building
Washington, D.C. 20006
(202) 331-5000

15/ The undersigned certify, that, to the best of their knowledge and belief, this petition includes all data, information, and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Since this petition does not request agency action significantly affecting the quality of the human environment, an environmental impact statement is not required. 21 C.F.R. § 25.1.

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ROYAL COMMISSION ON

Capital Punishment

1949-1953

REPORT

Presented to Parliament by Command of Her Majesty
September 1953

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EXHIBIT 1

within the prison walls, than in America, where it is handed over to the next-of-kin. But we do not think the distaste so widely felt at the idea of mutilation or distortion comes from the thought of the pain that seeing it might cause the relatives; it is more deep-seated than that. In this aspect of "decency", then, the other methods have an advantage over hanging. But in assessing this factor—essentially an emotional one—we must not forget that, while hanging is tainted by the memory of its barbarous history, "gassing" is tainted by more recent but not less barbarous associations.

733. There is one other point we ought to mention before we state our conclusions on this comparison. We heard much about the psychological harm said to be caused indirectly by executions—their distressing, or some say brutalising, effect on those who have to carry them out, the nervous strain they impose on other prisoners in the gaol and the morbid interest they arouse in the public. These beliefs are generally adduced as one of the arguments for the abolition of capital punishment altogether, and, as such, are not our concern. But they would be relevant here if consequences of this sort could be shown to be the result less of the fact of execution than of its method. We shall later consider the question whether, if hanging continues, any changes ought to be made in the way it is done, and we shall then give our opinion on the extent to which the beliefs we have referred to are justified. Here it will be enough to say that we cannot regard them as a factor of any weight in our present comparison. No doubt the ambition that prompts an average of five applications a week for the post of hangman,[7] and the craving that draws a crowd to the prison where a notorious murderer is being executed, reveal psychological qualities of a sort that no state would wish to foster in its citizens. No doubt to assist at an execution is a trying experience for those whose duty it is. But we have no reason to suppose that these concomitants of capital punishment would be prevented or abated merely by substituting the electric chair or the gas-chamber for the gallows.

Conclusion

734. Having carefully weighed all the factors set out in the preceding paragraphs, and bearing in mind that, as we have said, the onus of proof lies heavily on the advocates of change, we cannot recommend that either electrocution or the gas-chamber should replace hanging as the method of judicial execution in this country. In the attributes we have called "humanity" and "certainty" the advantage lies, on balance, with hanging; and though in one aspect of what we have called "decency" the other methods are preferable we cannot regard that as enough to turn the scale.

New methods of execution

735. We have pursued our inquiry into the question whether there is any other method, as yet untried, that could be relied on to inflict death as painlessly and certainly as hanging but with greater decency, and without the degrading and barbarous associations with which hanging is tainted. Only two suggestions were made to us deserving serious consideration.[8] One is the use of lethal gas in a way that does not need a gas-chamber. The other is execution by means of a hypodermic injection of a lethal drug.

736. *Lethal gas without a gas-chamber.* Our rejection of the existing method of execution by lethal gas was based in part on its employment of the elaborate contrivance of a gas-chamber. We thought it right therefore

7. Mathews, Q. 409.
8. We have not thought it necessary to consider seriously the alternative of execution by some such weapon as a "humane killer"; we are sure that any such method would be abhorrent to public opinion.

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to consider the possibilities of execution by lethal gas administered in some other way. We were impressed by the opinion of the British Medical Association that if an alternative to hanging had to be found (though they did not advocate any change) gassing by carbon monoxide would be best. "A concentration of pure and odourless carbon monoxide", they said, "would cause loss of consciousness instantaneously and painlessly, followed rapidly by death."[9] But they recognised that what they called the "highly unpleasant historical associations" of gassing might rule out all variants of that method. In making their suggestion they had in mind the use of a gas-chamber, but we later discussed with other medical witnesses whether it would be practicable to dispense with one, and to administer the gas through a mask. Several objections to this were pointed out. It was said that the prisoner would not become unconscious for at least a minute after the first inhalation of the gas, and the interval would probably be longer because no one so treated could help holding his breath as long as possible: that forcibly to apply a mask to a conscious man would be to invite struggling, involuntary perhaps and certainly ineffective, but distressing and unseemly: that disagreeable incidents like these could only be avoided by making the prisoner unconscious first, and that if he were unconscious there would be no point in using gas; he would be despatched more simply and decently by a lethal injection. We find the objections conclusive.

737. *Lethal injection.* A lethal injection from a hypodermic syringe has not, so far as we know, been adopted anywhere as a method of judicial execution. But to those who accept our postulate that the only requisites are humanity, certainty and decency this is likely to be the alternative to hanging that first suggests itself. We discussed it with representatives of the British Medical Association and later in some detail with members of the Association of Anaesthetists who were good enough to give us the benefit of their special knowledge of the subject.

738. As is well known, injections commonly given in medical practice are of two kinds, intramuscular and intravenous. An intramuscular injection needs no special skill; anyone can learn to give one in a few minutes. An intravenous injection is a delicate and skilled operation. A lethal dose can be given either way, but only if it is given intravenously can it be certain that death will be both quick and painless. We shall therefore consider this method first. The drug, probably a barbiturate, such as hexobarbitone or thiopentone, would be injected into a vein, preferably at the bend of the elbow or the wrist. In about twenty or thirty seconds, perhaps before the dose was completed, the drug would reach the brain. The prisoner would then become unconscious and die a minute or two later. There would be no danger of failure if a large enough dose were given, and the prisoner would feel nothing after the prick of the needle. Except for the application of some form of restraint to prevent movement, the only preparation he would have to undergo would be the tying of a tourniquet round his arm, though it would be necessary, some time before the execution, to inspect his veins to make sure that the operation was unlikely to be impeded by any physical abnormality.

739. It appears then that intravenous injection, if practicable, would fulfil our three requisites better than any other method. But our expert witnesses questioned its practicability. The prison medical officers doubted even whether it was more humane than hanging:

> "2373. (*Chairman*) What are the objections that you see to a lethal injection?—(*Dr. Lauderst*) We do not think it would be any more humane, and we think the main objection is its impracticability.

9. p. 318 (31).

35a

2374. \ .ld you enlarge on that——?—It rai ithe question as to who is to do it, and how they are to do it. We cannot suggest who is to do it. We can think of ways it could be done, but looking at it from a wide angle we doubt if it would be any more expeditious than hanging.

2375. Anyway, you have fully considered that, and you have rejected any other method in favour of hanging,' which you think is the best form of execution?—Yes ".

The opinion of the British Medical Association' was:

" If it were practicable, the intravenous injection of a lethal dose of a narcotic drug would be a speedy and merciful procedure . . . But the practical difficulties encountered in many cases when injection into a vein is attempted are such as to render the method quite unsuitable for the purpose of execution ".

740. Later, with members of the Association of Anaesthetists, we went into the reasons why the method was called impracticable. Substantially they are three. First, it is impossible to give an intravenous injection to anyone with certain physical abnormalities. Secondly, it is never easy to give one except with the co-operation of the subject. Thirdly, the operation demands professional skill, which the medical profession would be unwilling to use for such a purpose.

741. As to the first of these, we were told that in some people the veins are so covered with layers of fat as to be invisible, and in others they are so flat that it is almost impossible to prevent a needle which has pierced one wall from going through the opposite one as well. These conditions are rare: it is estimated that, with a willing subject, abnormal physical characteristics of this sort might make venepuncture difficult in one in five hundred cases and impossible in one in three thousand. There is, however, the further difficulty that even normal veins may become flattened by cold or nervousness, a condition not improbable in the circumstances we have in envisage. The usual way of restoring the veins is to immerse the arm in hot water until they become rounded, a process that may take ten to fifteen minutes, and even then several attempts may be necessary before an injection can be successfully given.

742. As to the second, intravenous injection is so delicate an operation that it cannot be done quickly and certainly unless the subject keeps absolutely still. Even with the arm strapped to a splint, this may not be easy to secure with an unwilling subject.

" A vein is not like an artery, which has a fairly thick wall. It has a very thin wall, and the moment you touch a vein with a needle the two sides tend to go together, and therefore any movement will tend to let your needle go through both walls, or one side or the other, and even the slightest movement will deflect your needle ".[2]

743. The third reason for holding this method to be impracticable was put thus by the British Medical Association :[3]

" No medical practitioner should be asked to take part in bringing about the death of a convicted murderer. The Association would be most strongly opposed to any proposal to introduce, in place of judicial hanging, a method of execution which would require the services of a medical practitioner, either in carrying out the actual process of killing or in instructing others in the technique of the process ".

1. p. 318 (29). 2. Law. Q. 9935. 3. p. 318 (27).

744. It will be convenient to consider this last reason before the other two. We of course respect the attitude of the British Medical Association, but we think they may have magnified its probable consequences. A later medical witness thought that the profession would treat the question as one of individual conscience, and not all doctors would feel debarred from giving instruction for such a purpose. Moreover, it is not only within the profession that the necessary skill is to be found. There are many outside it who are fully competent either to give injections themselves or to train others to do it. Laboratory technicians engaged on research work that requires them to give intravenous injections to small animals become extremely skilful. No one can say beforehand to what extent it would be possible either to get volunteer executioners among persons already skilled, or to arrange for training unskilled persons to act as executioners and for giving them the constant practice in venepuncture necessary to maintain their skill. That there are plenty of potential difficulties is obvious. How many and how serious they would prove to be must remain conjectural until tested by experience ; we assume that, if this method of execution were to be introduced, the date when the change took effect would have to be left to be determined by administrative action, after time had been allowed for making the necessary arrangements. Our evidence does not justify a conclusion that the difficulty of getting executioners, if it were the only obstacle in the way of a desirable reform, would prove insuperable.

745. But it is by no means the only obstacle. The question raised by the first and second reasons admits of no easy answer. What is to be done if an intravenous injection is not feasible, or feasible only after delay and perhaps a struggle? A possible answer is that hanging should remain the standard method of execution, but that the condemned man, except in the rare cases where he is of unsuitable physique, should be offered intravenous injection as an alternative. If he chose it, he might presumably be relied on not to resist it. This is what our anaesthetist witnesses thought ought to be done.

" It should be offered as an alternative, pleasanter, method of execution, and should be used only when it has been willingly accepted ".[4]

746. This solution would have incidental advantages. It would afford a gradual and experimental way of introducing an untried system, and it might facilitate the provision of executioners, since what would be needed of them could be represented rather as an act of mercy than as an execution. But the contrary arguments are formidable. The practical disadvantages are easy to picture—the inequity of offering a choice to some that might have to be denied to others because of their physical characteristics, the vacillation that might be evoked in a prisoner by having to make so crucial a decision, a vacillation tormenting to himself and embarrassing to the authorities, and the need to have the hangman waiting in the background in case his services should be required after all, gradually perhaps losing his skill from disuse. Even more important, we think, in the argument that it is the duty of any state that inflicts capital punishment to decide for itself what is the proper method of carrying it out, to use that method invariably, and to take all possible means to ensure that the act is performed with dignity, solemnity, speed and certainty.

747. The argument thus points towards the conclusion that, if lethal injection were to be instituted as the method of judicial execution, intramuscular injection would have to be used when intravenous was not feasible.

4. p. 438A (7).

Intramuscular injection is always feasible. As we have said, it needs little skill, and death can be ensured as certainly as by venepuncture. Complete immobility is not necessary: an injection could be given in the thigh through a cut in the trousers, or the needle could even be put through the clothes. But the intramuscular method has the disadvantages that the injection of the fluid might be painful and that it works comparatively slowly. How much pain might be caused by a lethal dose, and how long it would take to be effective, no one, for obvious reasons, can say with certainty. But it seems clear that the time would be a matter of minutes rather than seconds: at best, execution by intramuscular injection would be an appreciably slower process than by venepuncture. We are thus brought back to the question, touched on in paragraph 736, whether a condemned man might be rendered unconscious before being executed. We discussed this with medical witnesses. A sedative to induce unconsciousness could be given either by intramuscular injection or by the mouth. The degree of pain that may be caused by an intramuscular injection depends mainly on the size of the dose: a sedative dose should not be as painful as a lethal one. But the injection of even a sedative dose might be accompanied by some pain: and if, to minimise this, the dose were reduced, it would take longer to act. For this reason a sedative given by the mouth would be preferable. This alternative, however—apart from the obvious difficulty that the draught might be refused—is said to be open to certain objections of principle. If the time for giving the dose were the morning of the execution, its administration would become in effect part of the process of execution, in which no doctor would think it right to participate. If the time were the night before, this too would require unprofessional conduct from any doctor asked to give it. No doctor (so we were told) could ever properly give to anyone a larger dose than the maximum ordinarily used for therapeutic purposes. Such a dose would not be enough to make sure that the condemned man would be unconscious in the morning. Individual reaction to drugs varies greatly, and to ensure unconsciousness in the morning it would be necessary to give a dose so strong that it might even prove fatal to anyone specially susceptible to the drug. Here arises another objection of principle. It was represented to us that, if death were thus caused unintentionally, by a method other than that prescribed by law, the Home Secretary might find himself in a most awkward predicament. This last objection, however, is legalistic, and could presumably be removed by an alteration of the law. Nor does there seem to be any great difficulty in meeting the objections based on the doctor's professional code, if arrangements could be made—as they presumably could—for the dose to be a pharmaceutically standardised one which could be prepared by a layman. There would still remain the difficulty that the condemned man might refuse the dose, and have to be made unconscious by intramuscular injection, perhaps not wholly painlessly.

748. Before ending our exposition of the facts and arguments bearing on lethal injection, we ought to mention an argument of a general kind put to us against the adoption of any such method of execution. It is akin to the argument in the passage we have quoted from the evidence of the prison chaplains. "If a man is to die, let him walk to his death cleanly". By general consent one of the prime requisites of any form of capital punishment is that it should admit of being so carried out as to minimise the risk of distressing and unseemly scenes of panic and resistance. Those of our witnesses who have the duty of attending executions gave striking and unanimous testimony to the stoicism with which condemned men—and women—almost always face death on the scaffold.

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Mr. Pierrepoint told us that in all his long experience he had known only one struggle, and that was at an execution of an alien convicted not of murder but under the Treachery Act.' The argument we are now concerned with rests on the belief, supported by this experience, that human nature is so constituted as to make it easier for a condemned man to show courage and composure in his last moments if the final act required of him is a positive one, such as walking to the scaffold, than if it is mere passivity, like awaiting the prick of a needle. We state this argument without comment, to complete the marshalling of our material. As with so many of the arguments on this topic, everyone will be disposed to judge it subjectively, according to his own idiosyncrasy.

Conclusion

749. It is not easy, on a question such as this, to reach conclusions solidly based on factual evidence and reasoned argument. Any assessment of an untried method of execution is bound to be largely conjectural, and subjective bias intrudes irresistably. Our own collective verdict must be a negative one: we cannot agree to recommend that in present circumstances lethal injection should be substituted for hanging as the method of judicial execution in this country. If we could have been satisfied that executions could be carried out in this way quickly, painlessly and decently in all cases, we should have recommended its adoption unanimously. But we are bound to conclude from our expert evidence that there is not at present a reasonable certainty of this. We do, however, recommend, unanimously and emphatically, that the question should be periodically examined, especially in the light of progress made in the science of anaesthetics, with a view to a change of system being proposed to Parliament as soon as it can be shown that there are no longer any grounds for the doubts that now deter us from recommending it.

Changes in the Present System of Executions

750. It remains for us to consider whether any changes are desirable in the law and practice governing execution by hanging in Great Britain, assuming that system to continue. We have already described how an execution is carried out; we will now set out the law and practice, and make any recommendations we have to make on each point as we come to it.

General responsibility for executions in England and Wales

751. The Capital Punishment Amendment Act, 1868, which, as we have seen, abolished public executions, enacted that they should take place within the walls of the prison in which the prisoner is confined. The responsibility for giving effect to the sentence of death rests with the Sheriff, who usually delegates this duty to an Under-Sheriff—a practice authorised by section 11 of the same Act. The Under-Sheriff appoints the executioner from a list of suitable persons drawn up by the Prison Commissioners. The prison authorities also appoint one or more assistant executioners, and are in practice responsible for the erection of the scaffold, the provision of the necessary equipment and all the preliminary arrangements. The executioner and assistant executioners are not members of the prison service and the executioner is paid by the Sheriff.

752. The date of the execution is fixed by the Sheriff for a day, other than a Monday, in the week following the third Sunday after the day on which sentence is passed. If there is an appeal, and it is unsuccessful,

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EXHIBIT 2

Manufacturers

Abbott Laboratories
North Chicago, Illinois 60064

Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park
North Carolina 27709

Eli Lilly and Company
307 E. McCarty Street
Indianapolis, Indiana 46225
P.O. Box 618
Indianapolis, Indiana 46206

Invenex Laboratories
5885 Lakehurst Drive
Orlando, Florida 32809

Squibb & Sons, Inc.
General Offices
P.O. Box 4000
Princeton, New Jersey

Prisons

Warden Al Murphy
Oklahoma State Penitentiary
P.O. Box 97
McAlester, Oklahoma 74501

Acting Warden Felix Rodriguez (through 12/31/80)
Warden Harvey Wimans (as of 1/1/81)
P.O. Box 1059
Santa Fe, New Mexico 87501

Warden Darcol Gardener
Idaho State Correctional Institution
P.O. Box 7309
Boise, Idaho 83707

Warden Billy McMillan
Ellis unit
Texas Department of Correction
Route 6
Huntsville, Texas 77340

EXHIBIT 2 (continued)

State Department of Corrections

Mr. W.J. Estelle, Jr., Director
Texas Department of Corrections
P.O. Box 99
Huntsville, Texas 77340

Mr. Larry Meachum, Director
Oklahoma Department of Corrections
3400 N. Eastern
P.O. Box 11443
Oklahoma City, Oklahoma 73111

Mr. Paul Shoemaker, Director
Adult Institutions
New Mexico Department of Corrections
and Rehabilitation
113 Washington Avenue
Santa Fe, New Mexico 87501

Mr. C.W. Crowl, Director
Idaho State Department of Correction
P.O. Box 7309
Boise, Idaho 83707

AFFIDAVIT OF DR. WARD CASSCELLS

CITY OF BOSTON)
) ss:
STATE OF MASSACHUSETTS)

I, Dr. Ward Casscells, on oath depose and say that I am co-author of the article "The Ethics of Medical Participation in Capital Punishment By Intravenous Drug Injection" (Attachment 1), herein adopted by reference, published in the January 24, 1980, edition of The New England Journal of Medicine. My curriculum vitae is attached (Attachment 2). The thesis of this article is that a physician's preparation, administration or supervision of a lethal injection would be a perversion of biomedical knowledge and skill for a nonmedical purpose which would violate the ethical principles of the medical profession and the medical practice act of any American jurisdiction. Since the publication of this article, several professional medical and psychiatric associations have formally adopted or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a legally authorized execution other than to make a determination or certification of death.

The American Medical Association's ("AMA") governing body, the House of Delegates, adopted the following recommendation of the AMA Judicial Council on July 22, 1980:

> "A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution."

This AMA guideline applies to members of the Oklahoma Medical Association who, as members of that "unified" professional organization, are also all members of the AMA.

The Council of the New Mexico Medical Association endorsed the AMA position on the non-participation of physicians in lethal injections on August 2, 1980.

The Idaho Medical Association's House of Delegates adopted a resolution on July 26, 1980, advising its members not to participate in legal executions by administration of a lethal substance because "it is contrary to medical ethics for a physician to take a human life under any circumstances." The Idaho Medical Association formally stated that "a physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

The Texas Medical Association Board of Councilors on May 11, 1977, declared that a physician, by virtue of the Hippocratic Oath, cannot take a life under any circumstances. The Board at that time unanimously agreed to adopt the following opinion:

> "A physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

This position was reaffirmed by the Board of Councilors in May 1980.

The Board of Trustees of the American Psychiatric Association ("APA") approved the following statement on June 20, 1980:

> "The physician's serving the state as an executioner, either directly or indirectly, is a perversion of medical ethics and of his or her role as healer and comforter.
>
> "APA therefore strongly opposes any participation by psychiatrists in capital punishment, that is, in activities leading directly or indirectly to the death of a condemned person as a legitimate medical procedure."

In addition to these recently adopted resolutions, general ethical principles of the medical profession have long condemned medical participation in lethal injections. The language of the Hippocratic Oath is quite specific:

> "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing. Neither will I administer a poison to anyone when asked to do so nor will I suggest such a course."

The modern version of the Oath, the World Medical Association's Declaration of Geneva, states, "even under threat, I will not use my medical knowledge contrary to the laws of humanity." This provision was adopted in 1948 in direct response to the atrocities committed by medical personnel in Nazi Germany. Several international organizations have also condemned the physician's participation as an instrument of the state in imposing punishment. At the Conference for the Abolition of Torture, held in Paris in 1973, the medical commission declared:

> "Medical and associated personnel shall refuse to allow their professional or research skills to be exploited in any way for the purpose of torture, interrogation, or punishment, nor shall they participate in the training of others for such purpose."

The Guidelines for Medical Doctors Concerning Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment in Relation to Detention and Imprisonment, otherwise known as the Declaration of Tokyo, adopted by the Twenty-Ninth World Medical Assembly of the World Medical Association in October 1975, also contains principles which would prohibit a physician's participation in a lethal injection.

Aside from the ethical principles of the medical profession which condemn a physician's participation in a lethal injection, a physician's preparation, administration or supervision of a lethal injection would not be normal medical practice but rather a perversion of biomedical knowledge and skill for a nonmedical purpose. No physicians are trained to prepare lethal "medications" for human administration; few, if any, physicians would have experience in administering poisons or medication overdoses continuously to the point of death.

It appears that licensing laws and ethical standards for nurses and medical technicians would prevent them from carrying out a lethal injection if physicians did not participate because such personnel do not have the authority to prepare or administer a drug dosage independent of a physician's

specific order or valid standing orders. Furtnermore, such personnel would be even less experienced than physicians in carrying out intentional lethal drug injections since they would be less likely to have worked with laboratory animals. The ethical principles which prohibit physicians from participating in a lethal injection would also make it improper for physicians to train persons to perform lethal injections, assuming physicians even possessed the skills and knowledge to provide the training.

Finally, it is by no means clear that lethal injection is a more humane means of execution than the traditional methods. Electrocution, for example, based on what medical science knows about the brain and the effect of electricity applied to the brain, is presumed to render one unconscious instantly. It is quite possible that electrocutions, although gruesome to watch, are less painful, quicker and more reliable than any drug injection. The same might be said of the gas chamber or even hanging, which the Report of the Royal Commission on Capital Punishment presented to the English Parliament in 1953 supported over lethal injection for a variety of reasons.

WARD CASSCELLS, M.D.

SUBSCRIBED and SWORN TO before me

this 12 day of December, 1980.

Ronald Aronson

Notary Public

My Commission Expires: Notary Public - Commonwealth of Massachusetts

Ronald Aronson

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platelet activation (as measured by ; let-aggregation tests) during exercise testing in patients with angina and further found that patients who were given the drug pyridinolcarbamate showed less platelet sensitivity to aggregating agents and had less evidence of cardiac ischemia (e.g., electrocardiographic changes and chest pain) during exercise testing. In contrast to these findings, Frishman et al. reported that the administration of aspirin eliminated the enhanced platelet sensitivity to adenosine diphosphate in patients with angina but had no effect on either exercise tolerance or the degree of ischemic ST-segment depression during exercise.[3] In the report of Green et al., patients (some of whom were taking aspirin) whose plasma PF-4 levels did not increase had the same degree of ischemic electrocardiographic changes as those with exercise-induced increases in PF-4 levels, although the degree of chest pain was less. Hence, current evidence leaves unanswered the question of whether platelets have a major role in mediating the ischemia-induced electrocardiographic changes of classical angina pectoris. However, platelets could well increase the degree of ischemia (i.e., produce more chest pain) in typical angina pectoris, and there is some evidence that platelet-derived thromboxane A_2 may initiate the coronary-artery spasm that is characteristic of variant (Prinzmetal's) angina.[4]

Do the findings of Green et al. have wider implications for the possible role of antiplatelet drugs in prophylaxis against the more serious consequences of ischemic heart disease — myocardial infarction and sudden death? Leaving aside for the moment the problem of choosing the proper antiplatelet drug,[1] there is considerable uncertainty about the mechanisms responsible for these acute events. A transmural myocardial infarction is frequently associated with thrombosis of a major epicardial vessel,[5] and it is highly likely that platelets could play some part in initiating this process. On the other hand, sudden cardiac death, which may accounts for two thirds of coronary-disease mortality, is generally due to ventricular arrhythmias[6] and is only infrequently associated with evidence for myocardial infarction and thrombosis of a major epicardial vessel,[7] although platelet aggregates in the microcirculation have been observed.[8] The clinical manifestations of ischemic heart disease are undoubtedly caused by many mechanisms, and platelets could well play a role in some of these. Hence, a means of identifying a subset of patients who are at risk of a platelet-induced cardiac event because of increased platelet sensitivity would be important and could be useful in designing clinical studies with antiplatelet drugs. The broader implications of the findings of Green et al. in angina pectoris will not be clear until we have a better understanding of the mechanisms involved in the clinical manifestations of ischemic heart disease and of the role of platelets in some of these manifestations.

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SOUNDING BOARD

THE ETHICS OF MEDICAL PARTICIPATION IN CAPITAL PUNISHMENT BY INTRAVENOUS DRUG INJECTION

FOUR states have now passed legislation that adopts a new method of capital punishment — death by drug injection. The method entails injection of a lethal dose of a drug prepared for that purpose and administered and monitored by medically trained personnel. The growing adoption of these programs raises serious ethical issues for American physicians about their continued and expanded participation in state-ordered execution of human beings for crimes.

THE NEW LAWS

Oklahoma and Texas became the first states to mandate the new system with laws passed almost simultaneously in the spring of 1977. Oklahoma's law provides that the death sentence be carried out by "continuous intravenous administration of a lethal quantity of an ultra-short acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician."[1]

Idaho and New Mexico have since enacted similar death-by-injection laws. Florida is very close to enacting such legislation, and other states are considering similar programs. The objectives of the laws are clear enough. It is expected, first of all, that the method will be considered less painful and thus more humane to the condemned prisoner.[2] Secondly, it is hoped that the new method will encourage more juries to vote the death penalty. An Oklahoma newspaper observed, "The most telling point in favor of the drug method is that it might restore the death penalty to

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ATTACHMENT 1

actual use." [7] A third objective is constitutional: it is hoped that statutes providing for execution by this method will be less apt to be struck down by the courts as "cruel and unusual punishment." [8] A fourth objective is economic: the method is considerably less expensive than death by electrocution or lethal gas (the construction of a gas chamber for official executions in Oklahoma was estimated to cost over $300,000[9]).

The total number of condemned persons subject to execution under these laws in these states plus Florida is by no means small. Florida ranks first in the nation with 139 men and one woman on death row. Texas is second with 119. Oklahoma is seventh with 19. Idaho with one is ranked twenty-third. New Mexico has no prisoners under the death sentence.

Roles of Medical Personnel

Medical professional participation in these programs can involve a variety of roles, from ordering the substance and preparing it for injection, to injecting the substance or ordering and supervising the injection by other medical personnel, to monitoring the administration and observing the prisoner throughout the continuous injection of the drug, and, lastly, to examining the prisoner and pronouncing his death.

The procedure in Oklahoma, for example, requires that the medical director of the Department of Corrections "shall order a sufficient quantity of the [toxic] substance." [6] It is provided that the drug be sodium thiopental combined with tubocurarine or succinylcholine or potassium chloride. None of the laws requires specifically that a physician personally administer the lethal dosage directly into the prisoner's body. However, none of the laws and none of the policies or procedures adopted in the four states precludes physicians from starting the injections. In Oklahoma it is provided that "a trained medical employee shall insert the catheter and other monitoring equipment." An examining physician is required to inspect the catheter and equipment and to determine "that the fluid will flow into the vein." All the laws require that death be pronounced by a licensed physician in attendance at the execution.

History

There is nothing new about medical participation in state executions. Doctors have been present at and have had roles in official executions for centuries. The guillotine was invented by a dedicated physician and social reformer who opposed the death penalty; the invention was thought to be a more humane method of killing.[1] In this country in 1887 a commission of physicians opposed execution by hanging because of its frequent bungling and resultant prolonged suffering and because it lowered the dignity of the law by its public spectacle. The commission recommended more humane forms of killing, including electrocution, cyanide poisoning, chloroform overdosing, and intravenous injection of morphine. They favored electrocution over the chemical methods.[1] Thomas Edison supported the use of electricity for executions.[2]

Physicians have also been strong and vocal opponents of capital punishment by any method. Among the best known have been Benjamin Rush, B. W. Richardson, Louis J. West, and Karl Menninger. West observed, however, that the voices of physicians were not successful in "inspiring suitable action" within the profession. He found this particularly regrettable because of the general respect in which physicians were held in America. West felt that a powerful move would be "a national medical declaration that henceforth it would be considered professionally unethical for a physician to lend his presence to an execution, even as an official examiner to certify the fact and time of death." [3]

Ethics

It is our contention that the ethical principles of the medical profession worldwide should be interpreted to unconditionally condemn medical participation in this new form of capital punishment.

The Hippocratic Oath itself is the foundation of this position. Its essential purpose was to identify the Greek group of physicians as healers who would never kill or harm their patients. The language is quite specific: "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing. Neither will I administer a poison to anyone when asked to do so nor will I suggest such a course." [4] The modern version of the Oath, the World Medical Association's Declaration of Geneva, states, "even under threat, I will not use my medical knowledge contrary to the laws of humanity." [5] This provision was adopted in 1948 in direct response to the atrocities that so recently committed by medical personnel in Nazi Germany.[1] The war-crimes trials after World War II were then still going on, and the defense of the physicians accused of crimes against humanity was uniformly that they were ordered officially to perform the actions under threat of personal punishment or loss of their positions. The defense was rejected as a violation of the moral imperative to refuse to kill or to harm the prisoners, or to take part in the atrocities in any way.

It is important to recognize that such practices have not been limited to one country or one time. In the Soviet prison camps, according to Solzhenitsyn:

> The prison doctor was the interrogator's and the executioner's right-hand man. The beaten prisoner would come to on the floor only to hear the doctor's voice: you can continue, the pulse is normal.... If the prisoner is beaten to death he signs the death certificate: 'diseases of the liver' or 'coronary occlusion.' He gets an urgent call to a dying prisoner and takes his time. And whoever believes differently is not kept on in the prison."

Amnesty International has documented the participation of physicians in recent years in the torture of prisoners in Chile, Iran, Paraguay, Portugal, and Argentina.[10] Clearly these are extremes. However, American physicians have aided long interrogations of accused persons by conducting medical examinations

No physicians are trained to prepare lethal "medications" for human administration; few, if any, physicians would have experience in administering poisons or medication overdoses continuously to the point of death. Thus, requiring a physician to prepare and to administer or to supervise such a procedure would not be normal medical practice; it would be a perversion of biomedical knowledge and skill for a nonmedical purpose. It would, in our judgment, violate the medical practice act of any American jurisdiction.

Supervision by a physician of the actual administration of the lethal dosage by other "employed medical personnel" should be equally condemned ethically and legally. The physician should not escape moral responsibility by ordering a subordinate to do what he or she may not properly do directly. As a practical matter, the physician would need to be ready to intervene should the nurse or technician have difficulty with the catheterization. The physician might be required to do a venous cutdown or to perform other medical emergency procedures.

Could other medically trained personnel take over and perform all actions to cause the death by injection? An Associated Press dispatch (*New York Times*, Dec. 9) indicates that the Oklahoma program will use three "volunteer medical technicians" to actually administer the injection. They will stand behind a barrier, and each will inject a substance into a tube running through the barrier and into the prisoner's body. One of the substances will be lethal; none of the volunteers will know which substance was the lethal dose. A Corrections Department official is quoted as saying it is "sort of a firing squad approach."

In analogous situations, legal reasoning in court cases has been to the effect that under these circumstances, rather than avoiding legal and moral responsibility, all three actors would be fully responsible for the death, since each understands and intends to kill if the lethal substance happens to be theirs at the time.

Nothing is said in the news item about who prepares the injection or inserts the instrument into the prisoner's body, or selects which of the three tubes will carry the properly prepared lethal dose. Also, nothing is said about who selects the "volunteers," or whether they are correctional employees.

The licensing laws and ethical standards for nurses and medical technicians would sanction no such independent action. Such personnel are authorized to perform medical interventions with patients only under a physician's specific order or valid standing orders. Furthermore, such personnel would be even less experienced in carrying out intentional lethal-drug administrations than physicians since they would be less likely to have worked with laboratory animals. The ethical principles cited earlier would make it improper also for physicians to train persons to perform inhumane treatment or punishment, even if the physicians possessed the skills and knowledge to provide the training.

On the basis of the positions taken above, we believe it would also be ethically improper for physicians to monitor the condemned prisoner's condition during the drug administration and to carry on this action to pronounce his death when heartbeat and respirations were found to be absent. To perform such a continuous role would be so intimately a part of the whole action of killing as to deny any consideration as a separate medical service. The international principles cited earlier make it improper for a physician to be present during the administration of torture or cruel or inhumane punishment. The medical presence gives the impression of moral sanction by the healing professions. To be both present and performing a monitoring role is worse. It is similar to the physician who examines the prisoner intermittently during torture or prolonged interrogation and pronounces him physically fit to continue his ordeal. The "continuous intravenous injection" ends only when the monitoring physician pronounces the condemned prisoner dead. The physician then becomes the instrument, the order, to stop the lethal action itself. There is no other way to describe this physician's role but as that of an active participant, a key human participant, in the execution.

Other Views

There may be medical colleagues who genuinely disagree with some or all of the positions taken above. Some will support capital punishment and will sanction various methods of quick, relatively painless execution. Some will support medical participation in executions in the interest of administering clinical services to the prisoner, or will support witnessing the execution to assure against unnecessarily harsh handling of the prisoner. To be sure, medicine has for centuries realized that one of its important functions is to comfort and relieve, when unable to cure. Should the dying prisoner be deprived of this service because of the personal qualms or political fears of the doctor? Does the condemned have no "right to health care"? Surely this is begging the issue, as the person soon to be killed by the state is hardly analogous to the dying patient, yet some physicians may well take this view, as was the case in Oklahoma, where some physicians helped initiate the bill.

Some physicians may see only the legislature, or the judge, or the prison official as the instrument or instruments of the death and will excuse employed physicians and technicians as only doing their jobs. Some may see the physicians as performing not a medical service but a civic duty for social good and the protection of the community. For example, physicians may certainly vote and sit on juries; in these instances however, they are not using their skills to take a life.

before and after such questioning to verify that the person is physically fit to be questioned, or have certified that the person is not under the influence of drugs taken previously. Physicians have pumped out the stomachs of arrested persons to recover drugs or other contraband. They have operated to remove bullets from prisoners' bodies against their wills in order to have the bullets examined in connection with a crime. Courts have later held some of these practices to be improper searches and in violation of the Constitution."[7]

International Ethical Principles

Various international bodies have considered these issues and have condemned medical professional participation, whether personally or in a supervisory capacity, in such practices as prolonged questioning, forced feeding, physical or mental torture, and ordered punishment. At the Conference for the Abolition of Torture, held in Paris in 1973, the medical commission declared: "Medical and associated personnel shall refuse to allow their professional or research skills to be exploited in any way for the purpose of torture, interrogation, or punishment, nor shall they participate in the training of others for such purpose."[8]

The most important of the international pronouncements came two years later, in October 1975, when the Twenty-ninth World Medical Assembly of the World Medical Association adopted the "Guidelines for Medical Doctors Concerning Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment in Relation to Detention and Imprisonment," otherwise known as the Declaration of Tokyo.[9] The preamble includes the statement: "The utmost respect for human life is to be maintained even under threat, and no use made of any medical knowledge contrary to the laws of humanity."

The Declaration contains six Principles, three of which are particularly relevant to our discussion. In Principle 1 it is stated that the doctor shall not countenance, condone, or participate in any practice of torture or inhumane or degrading procedure, no matter what the offense the person is charged with or convicted of having committed; murder or other capital offenses are not excluded from this provision. In Principle 2 the doctor is prohibited from providing "the premises, instruments, substances, or knowledge to facilitate the practice of torture or other forms of cruel, inhumane or degrading treatment or to diminish the ability of the victim to resist such treatment." The medical professional person who orders or prepares a chemical substance to kill a prisoner under sentence of death would be in direct violation of this principle. It would also be a violation to order or prepare "a short-acting barbiturate" designed to anesthetize the victim so as to cause coma and thus eliminate resistance or pain reaction to the accompanying administration of a lethal, painful drug. The last provision, Principle 3, relates to the presence by physicians at the administration of torture or inhumane or degrading treatment — it is strictly forbidden. This prohibition would seem to cover active medical participation by monitoring of the administration of a lethal drug as well as mere passive observation of torture or inhumane punishments.

The Declaration of Tokyo does not deal directly with capital punishment. Torture is defined in the Declaration, but no listing is given of all forms of inhumane treatment or punishment that are condemned as violations of the laws of humanity.

Capital Punishment

Many of the major nations of the world have eliminated capital punishment for crime, and others have severely limited its application. The United States Supreme Court in 1972 ruled that capital punishment was "cruel and unusual punishment" under the Constitution and laid down strict rules that would allow states to install such punishment only under limited conditions.[10] Justice Brennan, in his concurring opinion, wrote:

> The primary principle is that a punishment must not be so severe as to be degrading to the dignity of human beings....More than the presence of pain, however, is comprehended in the judgment that the extreme severity of a punishment makes it degrading to the dignity of human beings....When we realize why [former methods] have been condemned, however, we realize that the pain involved is not the only reason. The true significance of these punishments is that they treat members of the human race as nonhumans, as objects to be toyed with and discarded.

The various statutes adopted since this decision have been attempts to stay within the guidelines laid down by the Court. It has been argued that the death-by-injection statutes would be within the guidelines.[11] The mere fact that the method is new does not strike it down as unconstitutional. The phrase "cruel and unusual" is read cumulatively so that the new method must be unusually cruel and inhumane to violate the standard.[12]

Ethical, Legal, and Clinical Concerns Regarding the New Procedure

Physician or other medical participation in carrying out a death sentence by intentional, careful, skillful injection of a medically prepared substance into the veins of the prisoner seems to us to constitute a grievous expansion of medical condonation of and participation in capital punishment. It is a more obvious application of biomedical knowledge and skills than any other method of execution yet adopted by any other nation in modern history. The preparation of the substance, either of a toxic nature alone or in combination with hypnotics or analgesics, would require special knowledge and skills in pharmacology and toxicology. Yet to call such planned killing a medically acquired skill would, we submit, be erroneous.

Conclusion

The medical profession should examine seriously the issues presented by this new method of capital punishment. We believe that it presents the most serious and intimate challenge in modern American history to active medical participation in state-ordered killing of human beings. Unlike any other methods, this procedure requires the direct application of biomedical knowledge and skills in a corruption and exploitation of the healing profession's role in society. We are also disturbed that this method, viewed as less cruel than other methods of capital punishment, should, by its availability, encourage the more extensive application of the death penalty and its recommendation by lay juries in the criminal courts. The line should be drawn here. The medical profession in the United States should formally condemn all forms of medical participation in this method of capital punishment.

William J. Curran, J.D., LL.M., S.M.Hyg.
Ward Casscells, M.D.

Harvard Medical School
Boston, MA 02115

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MASSACHUSETTS MEDICAL SOCIETY

Deaths

Robertson — George Joseph Robertson, M.D., of Seigwick Lubec, Maine, died on February 22, 1979. He was in his 64th year.

Dr. Robertson received his degree from Tufts College Medical School in 1943. He served as assistant dean for medical education for Tufts University School of Medicine and was medical director of its Bingham Program. He also served as medical director of Sisters Hospital and director of medical education at Thayer Hospital. He was former president of the Massachusetts Society of Internal Medicine and was a member of the American Rheumatism Association, the American Society for Internal Medicine, and the American Medical Association.

He is survived by his wife, four daughters and three sons, and three grandchildren.

Rockwell — Llewellyn Harrison Rockwell, M.D., formerly of Belmont, died on January 20, 1979. He was in his 86th year.

Dr. Rockwell received his degree from Tufts College Medical School in 1918. He served with the Army Medical Corps during World War I. He was chief surgeon at the Choate Memorial Hospital and was a member of the American College of Surgeons, the American Medical Association, and a Master member of the Massachusetts Medical Society.

He is survived by his wife, a daughter and a son, a brother and one grandchild.

Rogers — Howard Wooding Rogers, M.D., of Newburyport, died on May 2. He was in his 78th year.

Dr. Rogers received his degree from Columbia University College of Physicians and Surgeons in 1930. He served with the Army Medical Corps during World War II. He was a member of the American Medical Association and was a past president of the Essex North District Medical Society.

He is survived by his wife, two sons and five grandchildren.

Rozzela — Stanley J. Rozzela, M.D., of Duxbury, died on October 3, 1978. He was in his 42d year.

Dr. Rozzela received his degree from Hahnemann Medical College in 1963. He was a member of the American Diabetes Association and the American Medical Association.

He is survived by his wife, his mother and father, three brothers and two sisters.

Shapiro — Nathan Shapiro, M.D., of Randolph, died on December 1, 1978. He was in his 70th year.

Dr. Shapiro received his degree from the College of Physicians and Surgeons, Kansas City, in 1942. He was the physician for the Randolph Police Department and for the Massachusetts Racing Commission.

He is survived by his wife, two daughters, and one brother.

Shaw — Arnold Shaw, M.D., of Belmont, died on June 3. He was in his 76th year.

Dr. Shaw received his degree from Tufts College Medical School in 1928. He served as a clinical professor of surgery at Tufts University Medical School and at Harvard Medical School. He was a member of the American College of Surgeons, the International Society of Surgery-American Branch, the American Physicians Fellowship, and the American Medical Association.

He is survived by his wife, a daughter, five sons, four brothers and a sister.

CURICULUM VITAE

Samuel Hard Casscells, III

Date of Birth: March 18, 1952

Place of Birth: Wilmington, Delware

Citizenship: United States

Address: 64 Garfield Street, Cambridge, MA 02138

Marital Status: Married to Stephanie H. Taylor

Education:

1974	B.S. Yale University, New Haven, Connecticut (Biology, Cum Laud
1979	M.D. Harvard Medical School, Boston, Massachusetts (Magna Cum L
1979-80	Intern in Medicine, Beth Israel Hospital, Boston, Massachusetts
1980-	Resident in Medicine, Beth Israel Hospital, Boston, Massachusett
1980-	Resident in Medicine, Harvard Community Health Plan, Boston, Mas

Prizes:

1978 Leon Resnick Prize for Research

Memberships:

American Heart Association
Aesculapion Society, Harvard Medical School
Harvard Medical School Admissions Committee (1978-1979)

Boards:

National Board of Medical Examiners, Parts I, II, III

Publications:

1. Casscells W, Schoeneberger A, Graboys TB et al: Meralgia Paresthetica Due to Unusual Compression. N Engl J Med. 1978; 298:288.

2. Casscells W: Academic Affiliation and Physician Mortality. JAMA. 1978; 239:2116.

3. Casscells W: The "Tail" of Technology. Circulation. 1978; 58:379.

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4. Casscells W: Stress, Heart Disease, and Medical Students. Harvard Medical Alumni Bulletin, 1978; 52:56.

5. Casscells W, Taylor SH: Damned Lies. Lancet II, 1978; 687-688.

6. Casscells W et al: Interpretation by Physicians of Clinical Laboratory Results. N Engl J Med. 299:999-1001, 1978. (Reprinted in U.S. Public Health Service: Proceedings of the Clinical Quality Assurance Conference, Atlanta, USPHS, 1979; and in Sisson JA: Handbook of Clinical Pathology, 2nd ed., J.B. Lippincott, 1980.)

7. Falk R, Casscells W: Effects of Drugs on Myocardial Necrosis after Subarachnoid Hemorrhage. Brit Med J. 2:1501, 1978.

8. Casscells W, Verrier RL, Lown B: Influence of Phentolamine on Ventricular Vulnerability and Spontaneous Defibrillation in the Cat. Am J Cardiol, 1979 45:375.

9. Casscells W, Schoeneberger A, Graboys TB: Interpretation of Laboratory Tes N Engl J Med. 1979; 300:439-440.

10. Casscells W: Tracing Technology's Sway. Harvard Medical Alumni Bulletin 1979; 53:22-24.

11. Casscells W, Verrier RL, Lown B: The Repetitive Extrasystole Threshold: An Index of Vulnerability to Ventricular Fibrillation. Clin Res. 1979; 27:560.

12. Casscells W, Hennekens CH, Rosner B et al: Association of Retirement with Increased Mortality from Coronary Heart Disease. Circulation. 1979;60:11-15

13. Curran W, Casscells W: The ethics of Medical Participation in Capital Punishment by Intravenous Drug Injection. N Engl J Med. 1980; 302:226-230.

14. Casscells W, Hennekens CH, Evans D et al: Retirement and Coronary Mortality. Lancet. 1980; 1:1258-1259.

15. Casscells W: Prognosis After Myocardial Infarction. Brit Med J. 1980; 1:1

16. Casscells W, Verrier, RL, Lown B: Synergistic Antifibrillatory Effects of Phentolamine and Propranolol. Clin Res. 1980; 28:160.

In Press

17. Casscells W: Prognosis of Myocardial Infarction Versus Unstable Angina, N Engl J Med.

Submitted for Publication

18. Evans DA, Casscells W, Hennekens CH: Retirement and Coronary Disease.

19. Di Silva RA, Hennekens CH, Lown B, Casscells W: Lidocaine prophylaxis in acute myocardial infarction: an evaluation of study design.

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20. Casscells W, Goroll AH: Use of the Laboratory for Screening for Disease.

21. Casscells W, Verrier RL, Lown B: Influence of Alpha Adrenergic Blockade on the initiation and maintenance of ventricular fibrillation.

22. Casscells W, Verrier RL, Lown B: Synergistic antifibrillatory effects of Phentolomine and Propranolol in the dog and cat.

23. Casscells W, Verrier RL, Lown B: Mechanism of the antifibrillatory action of Phentolamine.

Current as of 11/80

AFFIDAVIT OF DR. RICHARD S. HODES

CITY OF TAMPA)
) ss:
STATE OF FLORIDA)

I, Dr. Richard S. Hodes, on oath depose and say, that I am a certified Diplomat of the American Board of Anesthesiology and a Fellow of the American College of Anesthesiology; a member of the American Society of Anesthesiologists, the Florida Society of Anesthesiologists and the Academy of Anesthesiology; former president of the Florida Medical Association; former president of the Florida Society of Anesthesiologists; former chairman of the Section on Clinical Care of the American Society of Anesthesiologists; former head of the Section on Anesthesiology at Tampa General Hospital where I founded and directed an approved residency program in anesthesiology; former Clinical Assistant Professor of Anesthesiology at the University of Florida, College of Medicine. I am currently Majority Leader of the Florida House of Representatives where I represent Florida's 68th District, Clinical Professor of Surgery at the University of South Florida, College of Medicine, and a practicing anesthesiologist. My curriculum vitae is attached (Attachment 1).

I am not aware of any published scientific data or information which in any respect address the use of sodium thiopental, tubocurarine, potassium chloride, succinylcholine, or any other drugs as a means of execution or which

establish their effectiveness for a quick, painless execution. Nor am I aware of any adequate and well-controlled investigation establishing their effectiveness as drugs for a lethal injection.

The intravenous injection of a lethal dosage of drugs would require professional skill in the actual administration of the drugs as well as in the determination of the necessary dosage. Execution by intravenous injection would require the placement of a needle or cannula into a vein prior to or immediately before the time of execution. Generally, such placement is more difficult in blacks, obese individuals and individuals with a long history of drug addiction. It would appear, as is the case in current clinical practice, that a standardized protocol cannot be constructed to insure uniform and equal treatment of all individuals. For the cannula to be maintained in position after placement in a resisting individual, constant restraint would be required. Similarly, a needle injection into a vein at the time the drug is injected would be considerably more difficult and unreliable in a resisting individual.

Whether a needle or a cannula is used, there is a risk of extravasation of drugs into the surrounding tissues causing considerable pain and discomfort. As a result of such an occurrence, the drug would not produce its intended result.

A major difficulty of injection as a means of execution is the fact that individual responses to drugs such as thiopental are quite varied. An individual with a long history of exposure to drugs or alcohol might not even lose consciousness with as much as one-half gram. This dose requires a large 20cc syringe since a greater than two and one-half percent concentration produces vein irritation and pain due to the highly alkaline nature of the substance. It is therefore reasonable to state that there can be no positive assurance that individuals would be rendered unconscious in all cases before the paralytic drug is injected. In almost all instances there would be an awareness of the onset of loss of consciousness. In the conscious individual, curare will produce a sense of shortness of breath and suffocation. An awareness is present since the effect is gradual with an onset over a two to three minute period. The effect of succinylcholine in the conscious individual is at first a sensation of multiple electric shocks over the entire body with erratic muscle twitching followed by acute paralysis and suffocation.

Even in the most well-controlled clinical situations, miscalculations as to the depth of unconsciousness produced by thiopental have been made. It would be reasonable to anticipate that in the excited individual facing execution the likelihood of this error is substantially greater. There is insufficient data to allow the use of

sodium thiopental, succinylcholine chloride, tubocurarine, potassium chloride and the other drugs cited as possible alternatives, as a so-called quick and painless means of execution.

Richard S. Hodes
RICHARD S. HODES, M.D.

SUBSCRIBED and SWORN TO before me
this 11th day of December, 1980.

Yvonne L. Mathis
Notary Public

My Commission Expires: July 19, 1983

Richard S. Hodes
238 East Davis Blvd.
Suite H
Tampa, Florida 33606

Curriculum vitae

Richard S. Hodes, M.D.

Born: April 24, 1924, New York, New York

Education:
- Miami Beach High School 1940
- Tulane University, B.S. 1944
- Tulane University School of Medicine, M.D. 1946
- Internship: U.S. Marine Hospital Staten Island, N.Y. 1946- 1947
- Fellowship: Anesthesiology Univ. of Minnesota 1949- 1951

Military: Army of United States 1947- 1949
1st Lieutenant to Captain

Professional: Private Practice - Anesthesiology
Tampa, Florida 1951 to present

Professional Associations and Activities

Academic Positions:

Head, Section on Anesthesiology
Tampa General Hospital 1958-1964
Founded and directed approved residency program in Anesthesiology

Clinical Associate - Anesthesiology 1961-1967

Clinical Assistant Professor - Anesthesiology 1967-1973
University of Florida, College of Medicine

Clinical Professor of Surgery
University of South Florida
College of Medicine 1973 to present

Professional Associations and Activities cont'd.

Member:
American Medical Association
Florida Medical Association
Hillsborough County Medical Association
American Society of Anesthesiologists
Florida Society of Anesthesiologists
Academy of Anesthesiology

Certified:
American Board of Anesthesiology
American College of Anesthesiology

Offices:
President, Florida Society of Anesthesiologists - 1960
Chairman, Section on Clinical Care, American Society of Anesthesiologists
Treasurer, Florida Medical Association 1975-78
Treasurer, Florida Physicians' Insurance Reciprocal 1975 to date
President, Hillsborough County Medical Association 1977
President, Florida Medical Association 1979-80
Medical Director, Professional Foundation for Health Care, Inc. 1980 to date

Public Affairs:

Elected to Florida House of Representatives, 1966 - to present District 68

Chairman of the Committee on Health & Rehabilitation Services 1968-74
Chairman of the Education Committee 1974-76
Chairman of the Legislative Staff Intern Program 1974 to date
Subcommittee Chairman, Appropriations Committee - Educational Appropriations 1978-80
Member, Rules Committee, Finance and Tax, Retirement, Personnel and Collective Bargaining 1978-80

Elected by the House as Speaker Pro Tempore 1978-80
Appointed by the House as Majority Leader 1981-83
Participant in the 1974 Washington Economic Summit Conference

Public Affairs:

National Organizations

President of the National Conference of State Legislatures, 1980

Chairman of the State Federal Assembly of the National Conference of State Legislatures, 1977

Chairman of the Human Services Resources Task Force of the Intergovernmental Relations Committee of the National Legislative Conference, 1974-76

Chairman of the National Resources Task Force of the National Legislative Conference, 1972-74

Member of the Task Force for the National Conference on State Small Business Programs, 1980 to date

Serves on the Intergovernmental Program Advisory Subcommittee of the National Science Foundation, 1980 to date

Health & Social Service Areas

Testified before various congressional committees on health and social services over the past 10 years. Representated the National Governors Conference giving testimony on social services revenue sharing before the Senate Finance Committee in 1974

Member of the Advisory Panel on National Health Insurance to the Subcommittee on Health of the Committee on Ways and Means of the United States House of Representatives, 1976 to date

President of the Board of Directors of the Human Services Institute for Children and Families, Arlington, Virginia, 1973-75

Education & Medical Education

Serves on the Advisory Committee for the Southern Regional Education Board, 1976 to date

Commissioner of the Education Commission of the States, 1975-76

Member of the Dean's Advisory Committee, University of South Florida College of Medicine, 1975 to date

Member of the Board of Fellows of the University of Tampa, 1976 to date

Others

Member of the Board of Directors, Florida West Coast Public Broadcasting, Inc., 1978 to present

Host of a weekly educational TV talkshow, "It's Your Government", WEDU, Tampa, 1975 to present

Member of the Board of Directors, Canterbury Towers, 1979 to present

Member of the Board of Directors of the Hillsborough County Association for Retarded Citizens, 1968-72

As a member of the Governmental Operations Committee was a major architect of the State Department of Health & Rehabilitative Services in 1969 during a constitutionally mandated executive reorganization. Served in the House of Representatives in 1968 when Legislature by resolution proposed a new constitution adopted by the people of Florida. Executive reorganization accomplished using Booz, Allen as management consultants.

Awards:

Recipient of the FEA/United of Florida Award for outstanding service to education, 1976, 1979, 1980

Award for recognition of health needs of the infants and children of Florida, the Florida Pediatric Society, Florida Chapter, American Academy of Pediatrics 1977-78

State Humanitarian award for outstanding community service from the National Conference of Christians and Jews, 1979

Legislative Service Award, Florida Association of Community Colleges, 1978, 1979

A. H. Robbins Community Service Award for outstanding community service by a physician, 1975

Nominated for the St. Petersburg Times Award in 1971, 1972,1975, 1976 as "Most Valuable Member of the House".

Florida Jaycees State Good Government Award, 1970

Distinguished Service Award, Florida Voluntary Health Association 1970

Awards cont'd.

Distinguished Citizen Award, Florida Association for Gifted Children, 1969

Award for distinguished service in the passage of historical 1968 Exceptional Child Legislation by the Florida Association for Retarded Children, 1968.

Publications:

Auxiliary Myocardial Vascularization by Prosthetic Graft Implantation, S. Smith, M.Beasly, R. Hodes & Others, Surg., Gyn, and Obs., 1957, 104: 263-268.

Legislative Evaluation of Human Resource Programs, R. Hodes, State Government, Vol. XLVII Summer 1974, No. 3, 175-179.

Maimonides: Physician, Philosopher, Jurist R. Hodes, Journal of the Florida Medical Assn., Sept. 1975, 43-45

Published proceedings of the 1975 Legislative Work Conference of the Southern Regional Education Board held in Biloxi August 27-29, 1975. Topic: Efficiency and Effectiveness in Higher Education, Paper: Should Faculty Workload Be Prescribed? R. Hodes, pp. 15-17.

The Real World for Doctors, R. Hodes, Journal of the Florida Medical Assn., July 1976, 558-560.

Response To A Public Policy Process, R. Hodes, Evaluation, 1976, 3:1-2, 82-83.

AFFIDAVIT OF DR. LEROY DAVID VANDAM

CITY OF BOSTON)
) ss:
STATE OF MASSACHUSETTS)

I, Dr. Leroy David Vandam, Ph.B. (Brown University, 1934), M.D. (New York University, 1938), M.A. Hon. (Harvard University, 1968), on oath depose and say that I have extensive training in pathology, surgery, surgical research, anesthetic and pharmacological research, writing, teaching and academic work. My curriculum vitae and bibliography are attached. I am currently Professor of Anesthesia, Emeritus, at Harvard Medical School, Anesthesiologist to the Peter Bent Brigham Hospital in Boston and Director of Anesthesiology at the Hospital at Parker Hill in Boston, a hospital run by the Harvard Community Health Plan.

I am not aware of any published scientific data or information which in any respect address the use of sodium thiopental, tubucurarine, potassium chloride, succinylcholine chloride or any other drugs as a means of execution or which establish their effectiveness as drugs for a quick, painless execution. Nor am I aware of any adequate and well-controlled investigations establishing their effectiveness as drugs for a lethal injection.

The intravenous injection of drugs, such as the short-acting barbiturate thiopental and the neuromuscular blockers succinylcholine and tubocurarine, requires a considerable amount of professional expertise. Even when such

an injection is performed by an expert, serious technical difficulties may arise causing the recipient physical and mental pain.

If a person is nervous or fearful, the veins become constricted as a result of sympathetic nervous activity, to wit, the release of adrenalin, thereby increasing the difficulty of performing the injection. Veins are difficult to find and enter in people suffering from obesity, people with heavily pigmented skin, elderly people with fragile veins, drug addicts whose veins may be thrombosed as a result of prior drug injections and people with a history of diabetes, uremia and some other conditions.

Insertion of a needle into a vein is always painful, even if a local anesthetic is first used. Repeated attempts at finding a vein cause pain and result in the escape of blood into the tissues, with swelling and occlusion of other veins.

In people with flat veins, it is impossible to prevent the needle which has pierced one wall from going through the opposite wall as well. If one of the drugs to be used for lethal injection were accidentally injected into an artery, a not unlikely occurrence, the recipient would experience excruciating pain, the artery would constrict and the surrounding tissues would die, probably with extensive gangrene.

Even if a needle seems to be within a vein, the drug might nevertheless escape into the surrounding tissue upon injection causing pain and swelling. Furthermore, as a result of the drug escaping into the surrounding tissue, the drug would not produce its intended result.

Thiopental is a highly alkaline solution of pH 11.5, which causes local thrombosis of the vein in some people. If it enters tissue, painful neuritis occurs if a nerve is adjacent, and tissue death may also occur. The same observations apply to potassium chloride and acidic solutions such as succinylcholine and tubocurarine.

The determination of the proper dosage of drugs for a lethal injection would also be a difficult task. When used as anesthesia, thiopental and curare are given intermittently in measured amounts until the desired effect is achieved. Even in the controlled setting of the hospital, however, it is not too unusual to have a patient recall operative events when presumably asleep and to experience pain. Dosage for a lethal effect would be determined by age, body mass, physical condition, and current and prior use of other drugs. Further, some people have inborn genetic responses to drugs which also influence dosage. If thiopental and tubocurarine were given in sequence, one might not be effective before the other. For example, if not enough thiopental were given and it were followed by curare, the

prisoner could be awake and he would die in physical and mental agony. This might also occur if the thiopental escaped into the surrounding tissue upon injection or were accidentally injected into an artery.

There is insufficient data to allow the use of sodium thiopental, succinylcholine chloride, tubocurarine, potassium chloride and the other drugs cited as possible alternatives, as a so-called quick and painless means of execution.

Leroy D Vandam MD
LEROY DAVID VANDAM, M.D.

SUBSCRIBED and SWORN TO before me
this 15th day of November, 1980.

Eleanor Jones
Notary Public

My Commission Expires: March 12, 1987

CURRICULUM VITAE

LEROY D. VANDAM, M. D.

BORN:	January 19, 1914, New York, New York
1934	Ph. B. (Magna cum Laude) Brown University
1938	M. D. New York University College of Medicine
1967	M. A. (Honorary), Harvard Medical School
1938-39	House Officer, Pathology, Beth Israel Hospital, Boston
1939-41	House Officer, Surgery, Beth Israel Hospital, Boston
1941-42	Research Resident, Surgery, Beth Israel Hospital, Boston
1942-43	Chief Resident, Surgery, Beth Israel Hospital, Boston
1942-43	Teaching Fellow in Surgery, Tufts Medical College
1943	First Lt., M. C., AUS, 4th Aux., Surgical Group
1943-45	Absence due to illness (September 1943-September 1945)
1945-47	Fellow in Surgery, Johns Hopkins University
1947-49	Resident in Anesthesiology, Hospital of the University of Pennsylvania
1949-50	Instructor in Surgery (Anes), University of Pennsylvania School of Medicine
1949-51	Associate in Surgery (Anes), University of Pennsylvania School of Medicine and Graduate School
1949-54	Physician Anesthetist, Hospital of the University of Pennsylvania
1950-54	Assistant Professor of Anesthesiology, University of Pennsylvania, Graduate School of Medicine
1951-54	Assistant Professor of Anesthesiology in Surgery, University of Pennsylvania
1953	Instructor in Anaesthesia - World Health Organization, Copenhagen
1954-57	Associate Clinical Professor of Anaesthesia, Harvard Medical School, Boston
1954-70	Surgeon, Peter Bent Brigham Hospital, Boston, Massachusetts
1954-70	Director of Anesthesia, Peter Bent Brigham Hospital, Boston
1956-74	Lecturer in Anesthesia, Chelsea Naval Hospital, Chelsea
1956-75	Chairman, Advisory Panel on Anesthesiology to the U. S. Pharmacopeia
1956-62	Associate Editor - Survey of Anesthesiology (Williams and Wilkins Co.)
1957-67	Clinical Professor of Anaesthesia, Harvard Medical School Boston
1958-	Editorial Board - Clinical Pharmacology and Therapeutics (C. V. Mosby Co.)
1960-	Editorial Board - G P

1952-54	Consultant in Anesthesia to: Valley Forge Army Hospital, Phoenixville, Pennsylvania Veterans Administration Hospital, Philadelphia, Pennsylvania
1954-	West Roxbury Veterans Administration Hospital, West Roxbury, Massachusetts Rutland Veterans Administration Hospital, Rutland Heights, Massachusetts Children's Hospital Medical Center, Boston, Massachusetts Boston Hospital for Women, Boston, Massachusetts Burbank Hospital, Fitchburg, Massachusetts Nantucket Cottage Hospital, Nantucket, Massachusetts Winchester Hospital, Winchester, Massachusetts Robert B. Brigham Hospital, Boston, Massachusetts Massachusetts Mental Health Center, Boston, Massachusetts Cambridge City Hospital, Cambridge, Massachusetts
1970	Beth Israel Hospital, Boston, Massachusetts
1934	Phi Beta Kappa
1934	Society of Sigma XI
1949	American Society of Anesthesiologists
1950	American Medical Association
1952	John Morgan Society - Pennsylvania
1952	Diplomate, American Board of Anesthesiology
1952	Fellow, American College of Anesthesiology
1954	New York Academy of Sciences
1954	Association of University Anesthetists
1954	Massachusetts Society of Anesthesiologists
1954	Massachusetts Medical Society
1954	New England Society of Anesthesiologists
1960	Aesculapian Club - Harvard Medical School
1960	Alpha Omega Alpha
1962	Academy of Anesthesiology
1962	International Anesthesia Research Society
1962	Fellow American College of Cardiology
1963-64	President, Massachusetts Society of Anesthesiologists
1963	Halsted Surgical Society
1964-65	President, Association University Anesthetists
1965	Horace Wells Award
1966	Honorary Member, Horace Wells Club
1974	American Arbitration Association
1975	International Medical Society of Paraplegia

1960	Visiting Professor, University of Iowa School of Medicine
1961-70	Editorial Board, Anesthesiology (J. B. Lippincott Co.)
1961	Visiting Professor, University of California School of Medicine, San Francisco
1961	Visiting Professor, College of Physicians and Surgeons, Columbia University
1961-70	National Research Council - Subcommittee on Anesthesia
1962-70	Editor-in-Chief, Anesthesiology (J. B. Lippincott Co.)
1963	Committee on National Halothane Study, National Research Council
1963-65	Training Grant Committee on Surgery, Radiology and Anesthesiology, National Institutes of Health
1964	Dr. Harry Shields Lecturer, Toronto, Canada
1965-66	Pharmacology and Toxocology Training Grant Committee, National Institutes of Health
1965	Visiting Professor, Albert Einstein College of Medicine
1965-70	Chairman, Committee on Anesthesia, National Research Council
1965-1966	Standing Committee on the Library, Harvard Medical School Visiting Professor, University of Florida College of Medicine, Gainesville
1966-70	Anesthesiology Training Grant Committee, National Institutes of Health
1966	Ad hoc Committee on Cardiopulmonary Resuscitation, National Research Council
1967-76	Chairman, Committee on Human Studies, Peter Bent Brigham Hospital
1967-	Professor of Anaesthesia, Harvard Medical School, Boston
1969-	Committee on Publications, Massachusetts Medical Society
1969-1970	Secretary, Department of Anaesthesia, Harvard Medical School Visiting Professor, University of Florida School of Medicine, Miami
1970-75	Committee of Ravision of The United States Pharmacopeial Convention, Inc.
1970-1971-	Anesthesiologist-in-Chief, Peter Bent Brigham Hospital, Boston Medical Advisory Board of the Medical Letter (Drug and Therapeutic Information, Inc.)
1972	Visiting Professor, Case Western Reserve University, Cleveland
1973	FDA - Consultant to the Advisory Committee on Respiratory and Anesthetic Drugs
1973	Visiting Professor, University of Florida School of Medicine Miami
1973	Committee on Women, Harvard Medical School
1974	Visiting Professor, University of Florida College of Medicine Gainesville
1974	Visiting Professor, University of Arizona Medical School, Tucson
1974	Wesley Bourne Memorial Lecturer, Montreal, Canada
1974	Committee on Human Studies, Harvard Medical School

1975	Stuart C. Cullen Visiting Professor-University of California San Francisco
1975	Leonard M. Monheim Memorial Lecturer-University of Pittsburgh Pittsburgh, Pennsylvania
1975	Crawford W. Long Lecturer, Atlanta, Georgia
1975	Visiting Professor, Albert Einstein College of Medicine, New York
1976-	Editorial Board, New England Journal of Medicine
1976-	Visiting Professor, University of California, Harbor General Hospital
1976	Visiting Professor, Johns Hopkins Hospital Medical School, Baltimore, Maryland
1976	Becton-Dickinson Oscar Schwidetsky Memorial Lecturer, Phoenix Arizona
1976-1977	Conflict of Interest Committee, Peter Bent Brigham Hospital Wisconsin Society of Anesthesiologists Lecturer-University of Wisconsin, Madison
1977	Visiting Professor-Hartford Hospital- Hartford, CT
1977	Annual Robbins Lecturer- Vanderbilt University, Nashville
1977	Distinguished Service Award, American Society of Anesthes
1978	Visiting Professor- The New York Hospital- Cornell Medical Center
1978	Visiting Professor- West Virginia University Medical Center Morgantown
1978	N.B. Anderson Lecturer- Case Western Reserve University, Cleveland, OH
1978	Visiting Lecturer - 24th Regional Meeting, Japanese Society of Anesthesiology, Osaka, Japan
1978	Massachusetts Governors Task Force on Libraries
1978	Mass. Dept. Public Welfare, Cost Effectiveness Committee on Analgesic Drugs
1978	Hyman Ilman Lecturer. Waltham Hospital
1979	Trustee, Boston Medical Library
1979	Southern Society of Anesthesiologists. Annual Lecturer
1979	Ralph Waters Lecture. Midwestern Anesthesia Conference
1979	Graduation Address. Peter Bent Brigham Hospital Nurses
1979	Bert B. Hershenson Memorial Lecture
1979	E.A. Rovenstein Memorial Lecture
1979	President, Boston Medical Library
1979	Committee on Admissions, Harvard Medical School
1979	Anesthesiologist-in-Chief, Harvard Community Health Plan

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January 12, 1981

The Honorable Patricia Roberts Harris
Secretary, Department of Health and
Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Lethal Injection, Docket No. 80P-0513/CP

Dear Secretary Harris:

This letter supplements the above-referenced petition pertaining to lethal injection filed on December 19, 1980. By way of this supplement, Jerry Joe Bird and Henry Martinez Porter, inmates at the Ellis Unit of the Texas Department of Corrections, and Alton Franks, Carl Morgan, Charles W. Davis and Robyn Parks, inmates at the Oklahoma State Penitentiary, all of whom are under sentence of death by lethal injection, join in the above-referenced petition and request that you take the action sought by this petition.

Sincerely,

Stephen M. Kristovich

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DEPARTMENT OF H[illegible] & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 7 1981

David E. Kendall, Esq.
Stephen M. Kristovich, Esq.
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Hill Building
Washington, D.C. 20006

Re: Docket No. 80P-0513

Dear Sirs:

This replies to your petition of December 19, 1980, as amended, regarding the contemplated use by several States of lethal injections in executing condemned inmates. Your petition notes that four States—Texas, Oklahoma, Idaho, and New Mexico—have enacted death penalty statutes that mandate the use of "lethal injection" as a means of execution. On behalf of a number of inmates who have been condemned to die by lethal injection, you request that the Food and Drug Administration (FDA) take the following actions:

1. Affix a boxed warning to the labels of the drugs specified in the State statutes stating that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

2. Prepare and send to the manufacturers of the drugs and to the prisons and departments of correction in Texas, Oklahoma, Idaho, and New Mexico notices advising that the drugs specified for use in an execution in those States' statutes or prison policies are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

3. Place an article in the Drug Bulletin advising that the drugs specified for use as lethal injections are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.

4. Adopt a policy and procedure for the seizure and condemnation from prisons or State departments of correction of drugs which are intended to be used as a means of execution.

5. Recommend the prosecution of manufacturers, wholesalers, retailers, and pharmacists who knowingly sell drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess, or use drugs for the unapproved use of lethal injections.

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EXHIBIT 9

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Your petition has been carefully reviewed. For the reasons given below, we conclude that the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction and, therefore, that FDA has no authority to take the actions your petition requests. Accordingly, your petition is denied.

Our conclusion that the use of lethal injection is not subject to our jurisdiction is supported by the relevant statutory provisions, by our current policy on the use of approved drugs for unapproved uses, and by a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems.

Your petition alleges that FDA has the authority and responsibility to prevent the use of approved drugs for the unapproved use of lethal injection, and cites several court cases as well as agency policy statements suggesting that FDA has regulatory authority over the promotion and use of drug products for purposes for which they are not shown to be safe and effective.

We agree that FDA has asserted jurisdiction over the promotion of drug products for purposes not included in the labeling for the products. In the cases cited in your petition (United States v. Evers, 453 F. Supp. 1141 (M.D. Ala. 1978); United States v. An Article of Drug * * * Diso-Tate, CCH Food Drug Cosmetic Law Reports ¶ 38.086 (E.D. La. 1976)), the agency took action to stop the promotion and use of certain products to treat disease conditions not indicated in the approved labeling for the product. The agency position on the legal status of approved labeling for prescription drugs, from which you quote extensively in your petition, was stated in a notice published in the FEDERAL REGISTER of August 15, 1972 (37 FR 16503).

Thus we do not dispute that FDA as a general matter has the authority and responsibility to regulate certain drug uses not indicated in the labeling for the products. However, we do not believe that such authority extends to the State-sanctioned use of lethal injection. The case law supports this conclusion. The Court of Appeals has now affirmed the Evers decision (United States v. Evers, 643 F.2d 1043 (5th Cir. 1981)). This ruling, which holds that a physician does not misbrand a drug while holding it for sale after shipment in interstate commerce when he or she promotes it for an indication for which its labeling lacks adequate directions for use, has negative implications for the decision in Diso-Tate as well. At present, therefore, we do not believe this line of cases provides support for your petition.

Even were the contrary true, the facts on which you base your petition would still differ from the facts in these cases. Primarily, the use of drugs for execution by lethal injection is authorized by State laws in

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each jurisdiction. No similar laws were extant in the Evers and Diso-Tate cases. The Federal Food, Drug, and Cosmetic Act (act) defers to State law in certain areas. The drug provisions of the act do not apply, for example, to drugs wholly in intrastate commerce; their regulation is left to the States. Additionally, as reflected in the agency's notice on the legal status of approved labeling, the act does not apply to the "practice of medicine," that is, the use of approved drugs, including their use for unapproved purposes, by physicians in the treatment of individual patients. While we do not characterize the use of approved drugs for execution by lethal injection as part of the practice of medicine, we believe there is a parallel between the State's role in licensing physicians who administer drugs for both approved and unapproved purposes, and what is essentially the State's decision to use approved drugs for the purpose of execution by lethal injection.

Finally, the prescription drug provisions of the act (21 U.S.C. 353(b)) depend also on State law to define who is licensed to administer prescription drugs under the act. On the basis of these factors, we believe we must defer to a State's choice to use approved drugs for the purposes of execution by lethal injection.

We do not say, of course, that provisions of State law that are contrary to the Federal Food, Drug, and Cosmetic Act are lawful. Under the Supremacy Clause of the Federal Constitution, for example, a State could not legitimize the unlawful shipment of an unapproved new drug in interstate commerce or prevent its misbranding after shipment in interstate commerce by authorizing its use. (See also section 202 of the Drug Amendments of 1962, Pub. L. 87-781, 76 Stat. 780.) However, the drugs in question here are lawfully in interstate commerce at all points in time. We believe the requirements of the Federal law have been satisfied.

Were FDA clearly to have jurisdiction in the area, moreover, we believe we would be authorized to decline to exercise it under our inherent discretion to decline to pursue certain enforcement matters. The unapproved use of approved drugs is an area in which the case law is far from uniform. Generally, enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions. Thus, as a secondary and separate basis of denial, we decline, as a matter of enforcement discretion, to pursue supplies of drugs under State control that will be used for execution by lethal injection.

Your petition also discusses United States v. Euthanasia D Regular (CCH Food Drug Cosmetic Law Reports) ¶ 38,263 (D. Neb. 1975)), suggesting that it involves a situation "directly analogous" to the use of lethal injection in executing human beings. We do not think the situations are in fact analogous. In addition to the obvious differences in the factual settings, the finding that the drugs in that case were new animal drugs,

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and subject to the act, was based in part on the fact that they were intended by their manufacturers to be used for euthanasia. No similar finding can be made here on the basis of the information before us.

Finally, your petition contains many arguments that challenge the safety of the use of these drugs as execution agents. Because we have determined that the Federal Food, Drug, and Cosmetic Act does not provide us with authority to declare unlawful the use by State governments of drugs for lethal injection, the information is not pertinent to our conclusion. It is more appropriately addressed to the State legislatures that have passed or may wish to consider this type of legislation.

Sincerely yours,

Arthur Hull Hayes, Jr., M.D.
Commissioner of Food and Drugs

cc:
Jack Greenberg
NAACP Legal Defense and
Educational Fund, Inc.

Anthony G. Amsterdam
Stanford University Law School

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STATUTES

21 U.S.C. 321(p)(1) provides in pertinent part:

For the purposes of this chapter-

(p) The term "new drug" means-

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use;

21 U.S.C. 331(b) provides in pertinent part:

The following acts and the causing thereof are prohibited:

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

21 U.S.C. 332(a) provides in pertinent part:

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction to restrain violations of section 331 of this title, except paragraphs (h)-(j) of said section.

21 U.S.C. 346a(i) provides in pertinent part:

(i)(1) In a case of actual controversy as to the validity of any order under subsections (d)(5), (e), or (l) of this section any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

21 U.S.C. 348(g) provides in pertinent part:

(g)(1) In a case of actual controversy as to the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

21 U.S.C. 355 provides in pertinent part:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

* * *

* * *

(d) As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

* * *

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside.

* * *

21 U.S.C. 360(g) provides in pertinent part:

(a)

Not later than thirty days after-

(1) the promulgation of a regulation under section 360c of this title classifying a device in class I or changing the classification of a device to class I or an

order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device.

(2) the promulgation of a regulation under section 360d of this title establishing, amending, or revoking a performance standard for a device.

(3) the issuance of an order under section 360d(b)(2) or 360e(b)(2)(B) 360(b)(B) of this title denying a request for reclassification of a device.

(4) the promulgation of a regulation under paragraph (3) of section 360e(b) of this title requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 360e(g)(1) or 360e(g) (2)(C) of this title.

(5) the promulgation of a regulation under section 360f of this title (other than a proposed regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device.

(6) the issuance of an order under section 360j(f)(2) of this title, or

(7) an order under section 360j(g)(4) of this title disapproving an application for an exemption of a device for investigational use or an order under section 360j(g)(5) of this title withdrawing such an exemption for a device,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order.

REPLY

BRIEF

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CLERK

No. 83-1878

In the Supreme Court of the United States

OCTOBER TERM, 1983

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY MEMORANDUM FOR THE PETITIONER

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REPLY MEMORANDUM FOR THE PETITIONER

Respondents' Memorandum in Response does not expressly state whether they believe that the government's petition for a writ of certiorari should be granted.[1] However, in opposing our application for an extension of time to file a certiorari petition, respondents stated: "We believe that a careful and plenary consideration of this case is plainly warranted, and in order not to delay the Court's review of the literally vital issues presented herein, we oppose the Government's unnecessary request for an extension of time" (App., *infra*, 2a). In light of this statement, as well as the contents of their response to the Petition, it

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[1]Compare Sup. Ct. R. 22.1, 34.1(j) (brief in response must contain "[a] conclusion, specifying with particularity the relief to which the party believes himself entitled").

appears that respondents have joined us in urging this Court to grant review.

Respondents agree with us (Memo in Response 13) that the decision in this case " 'squarely conflicts' with the Fifth Circuit's recent decision in *O'Bryan* v. *McKaskle*, 729 F.2d 991 (1984)."[2] Respondents also agree (Memo in Response 11) that this case "presents a significant public policy question with implications for the scope of authority of all federal agencies."[3] Thus, respondents appear to concur with our view that the criteria for granting certiorari are clearly present in this case. See Sup. Ct. R. 17.1(a) and (c).

---

[2]Respondents err in contending (Memo in Response 13) that *National Milk Producers Federation* v. *Harris*, 653 F.2d 339 (8th Cir. 1981), the second case in conflict with the decision below (see Pet. 7-8), is "plainly distinguishable." As noted in the Petition (at 8), agency action is exempt from judicial review under 5 U.S.C. 701(a)(2) when the governing " 'statutes are drawn in such broad terms that in a given case there is no law to apply' " (*Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 410 (1971), quoting S. Rep. 752, 79th Cong., 1st Sess. 26 (1945)). Respondents argue (Memo in Response 14) that the FDA's decision not to initiate enforcement action in *National Milk Producers* fell within Section 701(a)(2) because the FDA had conducted lengthy rulemaking proceedings and had adopted "an elaborate set of regulations" concerning the activity at issue. By contrast, respondents argue (Memo in Response 14-15), the FDA's decision in this case was judicially reviewable because the FDA had not promulgated any such standards. Respondents have turned the holding of *Overton Park* on its head. To the extent that agency regulations establish the law to apply, the regulations in *National Milk Producers* provide more law than the proposed preamble relied on in *Chaney*.

[3]Respondents disagree with us, however, concerning the characterization of the principal issue in this case. Respondents maintain (Memo in Response 11 & n.4a) that the question is one of "deregulation" —"whether the executive can implement a 'deregulatory' decision under the guise of enforcement discretion despite a contrary legislative mandate." As noted in the Petition (at 13-14), however, respondents have never pointed to any evidence that Congress intended to regulate the states' administration of capital punishment, either by "drugs" or "devices," when it enacted the Food, Drug, and Cosmetic Act. Consequently, there is nothing to "deregulate."

For these reasons and the reasons set forth in the Petition, it is therefore respectfully submitted that the petition for a writ of certiorari should be granted.

REX E. LEE
Solicitor General

THOMAS SCARLETT
Chief Counsel
Food and Drug Administration

JUNE 1984

DOJ-1984-06

APPENDIX

IN THE
SUPREME COURT OF THE UNITED STATES

MARGARET M. HECKLER, Secretary of Health & Human Services, Petitioner,	)	
v.	)	No. A-761
LARRY LEON CHANEY, *et al.*, Respondents.	)	

[Received Apr. 11, 1984]

OPPOSITION OF RESPONDENTS TO APPLICATION FOR EXTENSION OF TIME WITHIN WHICH TO FILE PETITION FOR A WRIT OF CERTIORARI

Respondents Chaney *et al.* oppose the Application for Extension of Time of the United States, which was received by respondents' counsel on April 10, 1984. The Solicitor General states no reasons to justify the granting of more time to prepare a petition for writ of certiorari, except the most *pro forma* ones. This Application is violative of Rule 29.3 which requires that a request for an extension of time shall state "with specificity" the reasons why the granting of an extension is thought justified.

Since the decision of the District of Columbia Circuit in this case, the Court of Appeals for the Fifth Circuit has come to a contrary conclusion in *O'Bryan v. McKaskle*, Nos. 84-2182, 84-2183 (March 29, 1984). We believe that a careful and plenary consideration of this case is plainly warranted, and in order not to delay the Court's review of the literally vital issues presented herein, we oppose the Government's unnecessary request for an extension of time.

Respectfully submitted,

/s/ David E. Kendall

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PETITIONER'S

BRIEF

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QUESTIONS PRESENTED

1. Whether the Administrative Procedure Act, 5 U.S.C. 701-706, authorizes judicial review of the Food and Drug Administration's decision not to regulate the states' use, in carrying out capital punishment by lethal injection, of drugs that have been approved for other purposes but that have not been found to be "safe and effective" as a means of causing death.

2. If the Food and Drug Administration's decision not to regulate the states' use of drugs in carrying out capital punishment by lethal injection is subject to judicial review, whether that decision was arbitrary and capricious.

PARTIES TO THE PROCEEDING

Margaret M. Heckler, Secretary of Health and Human Services, is the only petitioner. In addition to Larry Leon Chaney, the respondents are Alton Franks, Carl Morgan, Charles W. Davis, Robyn Parks, Doyle Skillern, Jerry Joe Bird, and Henry Martinez Porter.

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In the Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1878

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-58a) is reported at 718 F.2d 1174. The opinion on denial of rehearing (Pet. App. 59a-62a) is reported at 724 F.2d 1030. The opinion of the district court (Pet. App. 63a-79a) and the decision of the Food and Drug Administration (Pet. App. 81a-88a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on October 14, 1983. A petition for rehearing was denied on January 17, 1984 (Pet. App. 87a). By order of April 12, 1984, the Chief Justice extended the time in which to file a petition for a writ of cer-

tiorari to and including May 16, 1984. The petition was filed on that date and was granted on June 18, 1984 (J.A. 122). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTES INVOLVED

Relevant provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, and the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, are reproduced in an appendix to this brief (App., *infra*, 1a-2a).

STATEMENT

In recent years, numerous states have enacted statutes prescribing lethal injection of drugs as the method for carrying out the death penalty.[1] In this case, prison inmates sentenced to death by lethal injection in Texas and Oklahoma petitioned the Food and Drug Administration (FDA) to block their executions on the ground that the states proposed to employ drugs that had been approved by the FDA as safe and effective for medical purposes but not for human execution. J.A. 16-33. Respondents asserted that their execution by this means would violate the "misbranding" and "new drug" provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(k), 352, 355(a).[2] J.A. 20-22. They requested the FDA, among other things,[3] to "[a]dopt

[1] These statutes include: Ark. Stat. Ann. § 41-1352 (Supp. 1983); Idaho Code § 19-2716 (Supp. 1983); Ill. Ann. Stat. ch. 38, § 119-5 (Smith-Hurd Supp. 1984); Mass. Ann. Laws ch. 279, § 61 (Law. Coop. Supp. 1984); Mont. Code Ann. § 49-19-103(3) (1983) (prisoner given choice of hanging or lethal injection); Nev. Rev. Stat. § 176.355 (1979); N.J. Stat. Ann. § 2C:49-2 (West Supp. 1984-1985); N.M. Stat. Ann. § 31-14-11 (Supp. 1983); N.C. Gen. Stat. § 15-187 (1983) (choice of lethal gas or lethal injection); Okla. Stat. Ann. tit. 22, § 1014 (Supp. 1983); S.D. Codified Laws Ann. § 23A-27A-32 (Supp. 1984); Tex. Code Crim. Proc. Ann. art. 43.14 (Vernon Supp. 1984); Utah Code Ann. § 77-18-5.5 (1983) (choice of firing squad or lethal injection); Wash. Rev. Code § 10.95.180 (Supp. 1984) (choice of hanging or lethal injection).

[2] The FDCA prohibits "the doing of any act" that results in a drug's being "misbranded" while it is "held for sale" (21 U.S.C. 331(k)). The FDCA also provides that a drug is misbranded "[u]nless its labeling bears * * * adequate directions for use" (21 U.S.C. 352(f)).

The FDCA prohibits the introduction of a "new drug" into interstate commerce or its delivery for introduction into interstate commerce unless it has been approved by the FDA as "safe and effective" (21 U.S.C. 355). A drug is considered to be a "new drug" if, inter alia, it is not generally recognized as safe and effective for use under the conditions "prescribed, recommended, or suggested in [its] labeling." 21 U.S.C. 321(p).

[3] Respondents requested that the FDA take the following actions (J.A. 32-33):

> 1. Affix a boxed warning to the labels of the drugs specified in the State statutes stating that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.
>
> 2. Prepare and send to the manufacturers of the drugs and to the prisons and departments of correction in Texas, Oklahoma, Idaho, and New Mexico notices advising that the drugs specified for use in an execution in those States' statutes or prison policies are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution.
>
> 3. Place an article in the *Drug Bulletin* [an FDA medical newsletter sent to physicians] advising that the drugs specified for use as lethal injections are not approved for use as a means of execution, are not considered safe and

a policy and procedure for the seizure and condemnation from prisons or state departments of correction of drugs which are destined or held for use as a means of execution" and to recommend the criminal prosecution of prison officials and others who "knowingly buy, possess, [sell] or use drugs for the unapproved use of lethal injections." J.A. 32-33.

The FDA declined to take the requested enforcement actions. It concluded (Pet. App. 81a-86a) that it had no jurisdiction under the FDCA to investigate the states' practice of administering lethal injections in capital punishment cases and that it would decline to take action in any event as a matter of its enforcement discretion. The Commissioner of Food and Drugs stated (*id.* at 82a, 85a):

> Our conclusion that the use of lethal injection is not subject to our jurisdiction is supported by the relevant statutory provisions, by our current policy on the use of approved drugs for unapproved uses, and by a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems.
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effective as a means of execution, and should not be used as a means of execution.

4. Adopt a policy and procedure for the seizure and condemnation from prisons or State departments of correction of drugs which are intended to be used as a means of execution.

5. Recommend the prosecution of manufacturers, wholesalers, retailers, and pharmacists who knowingly sell drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess, or use drugs for the unapproved use of lethal injections.

> Were FDA clearly to have jurisdiction in the area, moreover, we believe we would be authorized to decline to exercise it under our inherent discretion to decline to pursue certain enforcement matters. The unapproved use of approved drugs is an area in which the case law is far from uniform. Generally, enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions.

Plaintiffs then brought this suit for injunctive and declaratory relief in the United States District Court for the District of Columbia. J.A. 5-14. The district court dismissed the complaint on the ground that the enforcement decisions of an agency are not subject to judicial review. Pet. App. 63a-79a. Placing reliance on numerous cases involving enforcement discretion, including cases specifically involving the FDA, the district court concluded that "[i]t is by now well-established that decisions of executive departments and agencies to *refrain* from instituting investigative and enforcement proceedings are essentially unreviewable by the courts." Pet. App. 74a (emphasis in original). The district court added (*id.* at 76a):

> The record indicates that plaintiffs' petition was accorded careful consideration by the Commissioner, and his reasons for declining to initiate investigative and enforcement action were fully explained in a memorandum accompanying the denial of the petition. Whether the Commissioner might have reached a different decision in

> light of the political, scientific, and ethical controversy surrounding the use of prescription drugs to cause death by lethal injection is of no moment; the salient point is that under established authority the decision was his to make.

A divided panel of the court of appeals vacated the district court's judgment and remanded with directions "to order the agency to fulfill its statutory function" (Pet. App. 36a). The court of appeals concluded that the FDA has authority under 21 U.S.C. 331(k) to regulate the use of drugs in administering capital punishment. That provision prohibits the "misbranding" of drugs while they are "held for sale." The court apparently reasoned (Pet. App. 14a-15a) that the states' use of the drugs for an unapproved purpose constitutes "misbranding" and that the drugs are "held for sale" when they are injected into the person being executed.

The court of appeals also held that the FDA's decision not to initiate enforcement activity was subject to judicial review (Pet. App. 17a-30a). In the court's view (*id.* at 18a-22a), all agency action, including a decision not to begin enforcement proceedings, is presumptively reviewable except in those situations "where the governing statute is 'drawn in such broad terms that in a given case there is no law to apply'" (quoting S. Rep. 752, 79th Cong., 1st Sess. 26 (1945)). The court observed (Pet. App. 24a) that the "determination of whether there 'is law to apply' turns on such pragmatic considerations as whether judicial supervision is necessary to safeguard plaintiffs' interests, whether judicial review will unnecessarily impede the agency in effectively carrying out its congressionally assigned role, and whether the issues are appropriate for judicial review." In this case, the court found "law to apply" in the preamble to an FDA rule proposed for notice and comment in 1972 but never promulgated. The preamble stated (*id.* at 24a):

> Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the [FDA] is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. * * * When necessary the [FDA] will not hesitate to take whatever action * * * may be required to bring possible harmful use of an approved drug under control.

The court concluded (*id.* at 31a-35a) that the FDA's reasons for declining enforcement were irrational in light of the preamble and warned (*id.* at 37a): "We must be prepared to compel FDA to take action with respect to the [plaintiffs'] prayer for relief where an acceptable explanation of [FDA's] inaction is not promptly forthcoming."[4]

Judge Scalia dissented (Pet. App. 39a-58a), stating (*id.* at 39a) that the majority's decision constituted "a clear intrusion upon powers that belong to Congress, the Executive Branch and the states." He pointed out (*id.* at 46a) that "far from there being a 'presumption of reviewability' with regard to enforcement determinations, the well known pre-

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[4] Although the court of appeals acknowledged that "the state may take the life of a person as punishment" and that the "FDA is not responsible for the execution of these prisoners," the court observed that the "FDA's impermissible refusal to exercise enforcement discretion over the use of drugs for lethal injection * * * may also implicate the Eighth Amendment's prohibition of cruel and unusual punishment." Pet. App. 37a, 38a.

sumption is precisely the contrary." Finding no special circumstances justifying review in this case, Judge Scalia concluded that review was unavailable. He noted (*id.* at 48a-51a) that the preamble on which the majority relied was "full of flexible terms, the precise application of which was obviously intended to be, and could properly be, left to the discretion of the agency—for example, whether an unapproved use has become 'widespread.' "

Moreover, assuming that the FDA's decision not to undertake enforcement action was judicially reviewable, Judge Scalia found (Pet. App. 51a-58a) that the FDA's actions were not arbitrary and capricious. He concluded that the FDA had no statutory authority to take the requested action because "[u]nder no conceivable interpretation of the English language could [the drugs used in lethal injections] be deemed 'held for sale' " (*id.* at 55a).

By a five-to-five vote, the court of appeals denied the government's suggestion for rehearing en banc (Pet. App. 59a-60a).[5] In a statement joined by Judges Wilkey, Bork, and Starr, Judge Scalia stressed (*id.* at 60a) the significance of the holding of this case to "the enforcement authority of all federal agencies." Judge Scalia stated (*ibid.*) that the panel's finding of a "general presumption of reviewability" of enforcement decisions "distorts the law and usurps the authority of the Executive Branch." He also noted (*id.* at 61a) that the "pragmatic considerations" test referred to by the court of appeals was "not an application of the Supreme Court's

[5] Judges Wilkey, Ginsburg, Bork, Scalia, and Starr voted to grant rehearing en banc; Judges Wright, Tamm, Wald, Mikva, and Robinson voted against rehearing en banc. Judge Edwards abstained.

guidance, but the substitution of an entirely different test—which can be summarized by saying that we intervene when we think it a good idea."

INTRODUCTION AND SUMMARY OF ARGUMENT

A. In recent years, many state legislatures have concluded that the most painless and humane method of capital punishment is the use of lethal injections.[6] An increasing number of states have accordingly enacted statutes prescribing this method of execution. Respondents petitioned the Food and Drug Administration to block the use of lethal injections, but the FDA declined to intervene. However, the United States Court of Appeals for the District of Columbia Circuit reviewed the FDA's decision under the Administrative Procedure Act and concluded that the agency's reasons were arbitrary and capricious.

The impact of this decision on all administrative agencies can hardly be overstated. Prosecutorial and administrative enforcement decisions have traditionally been exempt from judicial review except in unusual circumstances. Thus, affirmance of the court of appeals' decision would cause substantial disruption of settled administrative practices and would "almost certainly result in the substitution of the preferences of the judicial branch for those of the executive." Pet. App. 39a (Scalia, J., dissenting).

[6] See, *e.g.*, Note, *Criminal Procedure—Capital Punishment —Texas Statutes Amended to Provide for Execution by Intravenous Injection of a Lethal Substance*, 9 St. Mary's L.J. 359, 361 (1977) (Texas lethal injection statute introduced "primarily because of a belief by proponents that death by lethal injection is more humane and more dignified than death by electrocution"); Gardner, *Executions and Indignities: An Eighth Amendment Assessment of Methods of Inflicting Capital Punishment*, 39 Ohio St. L.J. 96, 128-129 (1978).

Even if narrowly confined, affirmance would have deleterious consequences. The effect of the court of appeals' decision is to require the FDA to intervene in a highly controversial area far removed from its mission of protecting the consuming public from unsafe and improperly labeled drugs. Furthermore, unless reversed, that decision is likely to interfere with state enforcement of capital punishment statutes that satisfy Eighth Amendment standards. At a minimum, the use of lethal injections will be prevented until a manufacturer or other party seeks FDA approval for the use of the drugs in executions and demonstrates that they are "safe and effective" in causing death (21 U.S.C. 355(a)).[7] It is doubtful whether any manufacturer would seek such approval in view of the expense involved, the organized opposition to capital punishment, and the very small quantities of drugs that would be sold for this new use. Thus, the practical effect of affirming the court of appeals' decision might well be to prevent executions

[7] The court of appeals held that the FDCA's misbranding provisions (21 U.S.C. 331(k), 352(f)) are violated when prescription drugs approved by the FDA for other purposes are employed for capital punishment, a use for which FDA approval has not been sought or granted. The court apparently concluded that the drugs are misbranded because their labeling does not bear "adequate directions for use" (21 U.S.C. 352(f)) in causing death. Such labeling could not accompany the drugs, however, absent the approval of a new drug application (21 U.S.C. 321(p)(1), 355; see also page 3 note 2, *supra*). By regulation (21 C.F.R. 201.100(c)(2)) a new drug must generally bear the labeling "authorized by [its] approved new drug application." See also *United States* v. *Articles of Drugs (Rucker)*, 625 F.2d 665, 675 (5th Cir. 1980). Accordingly, the drugs would have to be approved as safe and effective in causing death (21 U.S.C. 355) before they could be lawfully labeled for that purpose.

by lethal injection altogether. In that event, many states would probably return to what they have concluded are potentially more painful methods of capital punishment.

B. These adverse consequences need not be suffered, because the court of appeals' decision is plainly wrong. In holding that the FDA's exercise of enforcement discretion was subject to judicial review, the court departed dramatically from settled principles of administrative law.

The Administrative Procedure Act, 5 U.S.C. 701(a)(2), provides that final agency action is not subject to judicial review if it is "committed to agency discretion by law." This bar to judicial review applies where the governing "statutes are drawn in such broad terms that in a given case there is no law to apply." *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 410 (1971) (quoting S. Rep. 752, 79th Cong., 1st Sess. 26 (1945)).

This is a paradigmatic case in which there is "no law to apply." The Federal Food, Drug and Cosmetic Act does not command the FDA to take investigative or enforcement action whenever a statutory violation is alleged or found. Indeed, the Act does not even suggest the standards to be used by the FDA in determining whether and when to undertake such action. Instead, the Act confers upon the Commissioner of Food and Drugs a "broad discretion—broad enough undoubtedly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of law." *United States* v. *Sullivan*, 332 U.S. 689, 694 (1948). Because most statutes granting enforcement powers to administrative agencies are cast in similar terms, it is well established that agency enforcement decisions are rarely subject to judicial review.

The court of appeals held that the FDA's decision was reviewable because, in the court's view, the agency had "made law to govern and guide its discretion in regulating the unapproved use of approved drugs" (Pet. App. 24a). But the "law" upon which the court relied was the preamble to a rule that was issued for notice and comment but was never adopted by the agency. This preamble does not place any restrictions on the FDA's enforcement discretion. In the first place, the preamble has nothing to do with the subject of enforcement discretion. Its sole subject is the interpretation of the FDCA's provisions regarding the lawful use of approved drugs for unapproved purposes. In an effort to show that the preamble limits the agency's enforcement discretion, the court of appeals seized upon a single sentence of the preamble and took that language completely out of context.

Even if the preamble had discussed the issue of enforcement discretion, it would not have bound the agency or furnished a sufficient basis for judicial review. The preamble is not a legislative rule, and the FDA's regulations clearly provide that pronouncements such as the preamble do not impose any general legal requirements on the agency. 21 C.F.R. 10.85(j). Similarly, under accepted principles of administrative law, an agency is generally not bound by statements of this type, and there is no good reason for holding the FDA bound here. On the contrary, if informal agency statements regarding enforcement policy provided sufficient grounds for judicial review of enforcement decisions, agencies would be discouraged from explaining their enforcement policies or from issuing internal guidelines to ensure that their enforcement decisions are rational and consistent.

The structure and legislative history of the FDCA reinforce the conclusion that FDA enforcement decisions are not reviewable. Judicial review of such decisions would place an intolerable burden on the agency and would divert scarce resources from the agency's important regulatory responsibilities. In addition, the legislative history of the FDCA unequivocally shows that Congress intended the FDA to have unreviewable enforcement discretion.

C. Even if the FDA's decision was judicially reviewable, the decision was rational and should have been upheld.

1. The FDA concluded that it lacked authority under the FDCA to regulate the states' use of lethal injections for capital punishment. The agency's interpretation of the statute it administers is entitled to considerable deference and should have been sustained. Instead, the court of appeals held that the FDA had authority under the provisions of the FDCA prohibiting the "misbranding" of drugs or devices while they are "held for sale." The court theorized that the drugs are "held for sale" when they are forcibly injected into the person being executed. The statutory language lends no support to this surprising construction, and there is not a hint in the legislative history that Congress had any intention to regulate the methods used by states in carrying out lawful death sentences.

The peculiar nature of the court of appeals' construction is highlighted by the fact that the misbranding provisions apply equally to "drugs" and "devices" and the fact that the statutory definition of a device seems clearly to encompass many of the paraphernalia traditionally used for executions, such as the gallows and the electric chair. See 21 U.S.C.

321(h), 331(k). By the court's reasoning, the FDA presumably would be obliged to regulate the use of these devices as well.

2. Even if the FDCA could somehow be stretched to reach the administration of lethal injections for purposes of capital punishment, the FDA articulated sound reasons for declining to intervene. Regulating the methods of capital punishment used by the states, whether or not technically within the scope of the FDCA, is certainly far removed from the FDA's central responsibilities. The FDA acted reasonably in conserving its limited enforcement resources for matters more closely related to its principal mission. The FDA also declined to intervene based upon a proper respect for principles of federalism. Enforcement of the criminal laws is of course one of the oldest and most important state functions.

Finally, the FDA acted reasonably in relying on the absence of a "serious danger to the public health" (Pet. App. 85a). Unless the agency was prepared to regulate all forms of execution, the issue posed by respondents was not a question of "pain versus no pain, but rather pain of one sort substituted for pain of another—*and in all likelihood substitution of a lesser pain, since that is the principal purpose of the lethal injection statutes*" (Pet. App. 51a (Scalia, J., dissenting) (emphasis in original)).

ARGUMENT

I. THE FOOD AND DRUG ADMINISTRATION'S DECISION NOT TO REGULATE THE STATES' USE OF LETHAL DRUGS FOR CAPITAL PUNISHMENT IS NOT SUBJECT TO JUDICIAL REVIEW UNDER THE ADMINISTRATIVE PROCEDURE ACT

A. Prosecutorial And Administrative Enforcement Decisions Are Generally Exempt From Judicial Review

Under the Administrative Procedure Act, 5 U.S.C. 701(a)(2), final agency action is not subject to judicial review if it is "committed to agency discretion by law." This bar to judicial review applies where the governing " 'statutes are drawn in such broad terms that in a given case there is no law to apply.' " *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 410 (1971) (quoting S. Rep. 752, 79th Cong., 1st Sess. 26 (1945)).

Where statutes explicitly or implicitly impose standards governing the exercise of an agency's discretion, there is "law to apply," and judicial review is available under the APA to determine whether the agency has abused its discretion. 5 U.S.C. 706(2)(A). In *Overton Park*, for example, this Court held that the Secretary of Transportation's decision to route an interstate highway through a municipal park was subject to judicial review because the governing statutes specified the factors that had to be considered in making the decision. Indeed, the statutes expressly prohibited the use of parkland except in "the most unusual situations" (401 U.S. at 411).

Because the statutes empowering administrative agencies usually provide some law to apply, this Court has noted that Section 701(a)(2) represents a "very narrow exception" to the provisions of the

APA authorizing judicial review. *Overton Park*, 401 U.S. at 410. As the court of appeals correctly noted (Pet. App. 18a-19a), final agency action in general is presumptively reviewable. The court below erred, however, in refusing to recognize that this presumption does not apply in certain circumstances, including where efforts are made to obtain review of prosecutorial and administrative enforcement decisions. As Judge Scalia noted in dissent (Pet. App. 46a), "far from there being a 'presumption of reviewability' with regard to enforcement determinations, the well known presumption is precisely the contrary." Cf. *Block* v. *Community Nutrition Institute*, No. 83-458 (June 4, 1984), slip op. 8 ("The presumption favoring judicial review of administrative action is just that—a presumption" and may be overcome.).

Prosecutorial and administrative enforcement decisions have traditionally been committed to unreviewable executive discretion for two principal reasons. The first is the doctrine of separation of powers.[8] Under the Constitution (Art. II, § 3), it is the duty of the Executive, not the courts, to "take Care that the Laws be faithfully executed." Discharging this responsibility often involves making basic policy choices. An agency may decide that enforcement is most needed in certain areas rather than others and may target its efforts accordingly. An agency may also decide on policy grounds that one method of enforcement is preferable to available alternatives or that the previous pace of enforcement

[8] See, *e.g.*, *United States* v. *Ross*, 719 F.2d 615, 620 (2d Cir. 1983); *United States* v. *Torquato*, 602 F.2d 564, 569 (3d Cir.), cert. denied, 444 U.S. 941 (1979); *United States* v. *Johnson*, 577 F.2d 1304, 1307 (5th Cir. 1978).

should be accelerated or slowed down. "It would be idle to pretend that the conduct of government litigation * * is a wholly mechanical procedure which involves no policy choices whatever." *United States* v. *Mendoza*, No. 82-849 (Jan. 10, 1984), slip op. 7. Our system of government entrusts such choices not to the judiciary but to officials accountable directly or indirectly to the electorate. See *Chevron U.S.A. Inc.* v. *NRDC*, No. 82-1005 (June 25, 1984), slip op. 27. Judicial review of enforcement decisions thus has been precluded to avoid "judicial 'second-guessing' of * * * administrative decisions grounded in social, economic, and political policy." *United States* v. *Varig Airlines*, No. 82-1349 (June 19, 1984), slip op. 16 (discussing discretionary function exception to Federal Tort Claims Act).

Enforcement decisions are also committed to executive discretion because they characteristically involve complicated questions of administration that are ill-suited for review by the courts.[9] In deciding whether to undertake enforcement action, an agency must do far more than merely determine whether there is a sound factual and legal basis for proceeding. The agency must decide which enforcement strategy will best carry out its statutory mandate and must decide how to allocate its scarce resources. It must compare the importance and cost of various potential cases, as well as the likelihood of success in each of those endeavors. It must consider both the benefits of undertaking a particular enforcement action and the potential for deleterious consequences if

[9] See, *e.g.*, *Inmates of Attica Correctional Facility* v. *Rockefeller*, 477 F.2d 375, 380 (2d Cir. 1973); *Newman* v. *United States*, 382 F.2d 479, 480 (D.C. Cir. 1967).

the effort proves unsuccessful. After considering these and other factors, an agency may rationally decide to pursue any of a number of different enforcement policies. For example, it may concentrate on a few of the most important or most highly visible cases. Or it may decide to undertake action in a much larger number of cases. Evaluating the relevant factors and developing a sound enforcement strategy are quintessentially the functions of a regulatory agency. They are not appropriate for judicial review.

Because of these considerations, it has long been the rule that prosecutorial and administrative enforcement decisions generally are not reviewable. This Court has repeatedly held that prosecutorial decisions are exempt from judicial review. *United States* v. *Batchelder*, 442 U.S. 114, 124 (1979); *Bordenkircher* v. *Hayes*, 434 U.S. 357, 364 (1978); *United States* v. *Nixon*, 418 U.S. 683, 693 (1974); *Linda R.S.* v. *Richard D.*, 410 U.S. 614, 619 (1973). See also *Newman* v. *United States*, 382 F.2d 479 (D.C. Cir. 1967) (Burger, J.). Cf. *Oyler* v. *Boles*, 368 U.S. 448, 456 (1962).

The Court has treated civil and administrative enforcement decisions in like manner, since "[t]he decision to initiate administrative proceedings * * * is very much like the prosecutor's decision to initiate or move forward with a criminal prosecution." *Butz* v. *Economou*, 438 U.S. 478, 515 (1978). As long ago as the *Confiscation Cases*, 74 U.S. (7 Wall.) 454 (1869), this Court held that the Attorney General had unreviewable discretion to decline to bring suit seeking condemnation of a vessel used to aid the Confederacy during the Civil War. In *FTC* v. *Klesner*, 280 U.S. 19 (1929), the Court concluded that

the Federal Trade Commission had unreviewable discretion to decline to pursue a citizen complaint of an alleged unfair trade practice. Writing for the Court, Justice Brandeis observed that "[a] person who deems himself aggrieved by the use of an unfair method of competition * * * may of course bring the matter to the Commission's attention and request it to file a complaint. But a denial of his request is final. And if the request is granted and a proceeding is instituted, he does not become a party to it or have any control over it." *Id.* at 25-26 (footnote omitted).

Enactment of the APA did not change this rule. The Court has concluded that the general counsel of the National Labor Relations Board has unreviewable discretion to decide whether to bring an unfair labor practice complaint before the Board. *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. 132, 138 (1975); *Vaca* v. *Sipes*, 386 U.S. 171, 182 (1967).[10] In *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411 (1958), the Court observed that the FTC was not required to proceed against all companies suspected of similar antitrust violations. The Court stated (*id.* at 413):

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[10] The court of appeals erroneously stated (Pet. App. 28a n.35) that the general counsel's decisions are unreviewable because 29 U.S.C. 153(d) explicitly precludes review. That provision states that "[t]he General Counsel * * * shall have final authority, *on behalf of the Board*, in respect of the investigation of charges and issuance of complaints" (emphasis added). The meaning of that provision is that the general counsel's decision is not subject to *administrative* review. The Board has delegated to him the authority to make the final administrative decision on its behalf. The opinion in *NLRB* v. *Sears, Roebuck & Co.*, 421 U.S. at 138, cited the statute to support this point, and it cited *Vaca* v. *Sipes*, *supra*, on the issue of judicial review.

> [A]lthough an allegedly illegal practice may appear to be operative throughout an industry, * * * whether all firms in the industry should be dealt with in a single proceeding or should receive individualized treatment are questions that call for discretionary determination by the administrative agency. * * * [T]he Commission alone is empowered to develop that enforcement policy best calculated to achieve the ends contemplated by Congress and to allocate its available funds and personnel in such a way as to execute its policy efficiently and economically.[11]

See also *New Jersey* v. *United States*, 168 F. Supp. 324 (D. N.J. 1958), aff'd, 359 U.S. 27 (1959);[12] *Panama Canal Co.* v. *Grace Line, Inc.*, 356 U.S. 309 (1958).

More recently, in *Southern Ry.* v. *Seaboard Allied Milling Corp.*, 442 U.S. 444 (1979), this Court held that the courts could not review the Interstate Commerce Commission's decision not to investigate charges

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[11] The Court stated (355 U.S. at 414) that the question whether the proceedings in a particular case should be held in abeyance pending anticipated future proceedings against competitors was reviewable to determine whether there had been a "patent abuse of discretion." Obviously the timing of such proceedings might affect the companies' relative competitive advantage. That is an entirely different question from whether a decision not to take enforcement action is reviewable.

[12] In *New Jersey* v. *United States*, *supra*, the Court summarily affirmed a decision holding that the Interstate Commerce Commission had unreviewable discretion to decline to investigate a railroad's proposed suspension of service. The three-judge court had held (168 F. Supp. at 329) that the ICC's decision was agency action committed by law to agency discretion.

by shippers that certain railroad rates were illegal. See also *City of Chicago* v. *United States*, 396 U.S. 162, 165 (1969). The Court in *Southern Ry.* noted (442 U.S. at 455) that the statutory provision governing the ICC's investigative power "is written in the language of permission and discretion" and that "[t]he statute is silent on what factors should guide the Commission's decision." The Court also relied on the structure and legislative history of the Interstate Commerce Act (*id.* at 456-460). As we will show, these same factors clearly demonstrate that the FDA's decision in the present case is likewise exempt from judicial review under the APA.

The weight of lower court authority also holds that administrative enforcement decisions are not subject to judicial review. For instance, in *National Milk Producers Federation* v. *Harris*, 653 F.2d 339 (8th Cir. 1981), dairy producers sought to compel the FDA to initiate "investigative, enforcement, or prosecutorial" proceedings against persons alleged to be violating the FDCA by selling misbranded cheese substitutes in interstate commerce. The court of appeals held (*id.* at 343):

> The executive branch and its departments enjoy a discretion in the initiation of * * * enforcement * * * actions limited only by constitutional strictures and relevant statutory directives.

Because the FDCA does not mandate enforcement actions, the court concluded (*id.* at 344) that a "complaint which seeks the initiation of investigative, enforcement, or prosecutorial proceedings fails to state a claim upon which * * * relief can be granted."

In *City of Seabrook* v. *Costle*, 659 F.2d 1371, 1374-1375 (5th Cir. 1981), the court held that the Environmental Protection Agency has unreviewable dis-

cretion to decline to find that a state implementation plan violates the Clean Air Act.[13] The court correctly reasoned (*id.* at 1374 (citations omitted)):

> The branches of government charged with the investigation of violations of the law and with enforcement of the law have traditionally been afforded broad discretion in carrying out these duties. We have held, for example, that the Attorney General's discretion "in choosing whether to prosecute or not to prosecute . . . is absolute." * * * The courts have recognized that, at least in the absence of a contrary statutory command, administrative agencies should be afforded similarly broad discretion. * * * This principle of almost absolute discretion in initiating enforcement action should apply with equal force to the decision to take the preliminary investigatory steps that would provide the basis for enforcement action.

See also *American Broadcasting Companies* v. *FCC*, 662 F.2d 155, 157-159 (2d Cir. 1981), and *American Broadcasting Companies* v. *FCC*, 682 F.2d 25, 30-31 (2d Cir. 1982) (no judicial review of Federal Communication Commission's refusal to suspend and investigate tariff filings).

The District of Columbia Circuit itself has similarly refused to permit judicial review of determinations by regulatory agencies not to initiate enforcement proceedings. In *Kixmiller* v. *SEC*, 492 F.2d 641 (D.C. Cir. 1974), the court held that the Securities and Exchange Commission's decision not to investigate the exclusion of certain materials from cor-

[13] Such a finding enables the EPA to issue a compliance order or initiate a civil action for injunctive relief or the assessment of a civil penalty. 42 U.S.C. (Supp. V) 7413.

porate proxy materials was not reviewable. The court wrote (*id.* at 645 (footnotes omitted)): "An agency's decision to refrain from an investigation or an enforcement action is generally unreviewable." In *Investment Co. Institute* v. *FDIC*, 728 F.2d 518 (D.C. Cir. 1984), the court refused to permit review of a determination by the Federal Deposit Insurance Corporation not to initiate cease and desist proceedings against a regulated bank for selling mutual fund shares through wholly owned subsidiaries. Holding that the matter was committed to agency discretion by law, the court noted (*id.* at 527) that "there is 'no law to apply' in reviewing a simple refusal to take enforcement action."

In departing from this longstanding authority holding that prosecutorial and administrative enforcement decisions are not subject to judicial review, the court of appeals relied principally upon *Dunlop* v. *Bachowski*, 421 U.S. 560 (1975). This Court's opinion in *Bachowski* did not even discuss Section 701(a)(2) of the APA, but in any event that case is easily distinguishable from the present case.

In *Bachowski*, a defeated candidate for union office sought to compel the Secretary of Labor to bring suit under provisions of the Labor-Management Reporting and Disclosure Act of 1959 (LMRDA), 29 U.S.C. 482(a) and (b), to have the election set aside. The Secretary argued that his decision was exempt from review under the APA both because "statutes preclude[d] judicial review" (5 U.S.C. 701(a)(1)) and because his decision was a matter "committed to agency discretion by law" (5 U.S.C. 701(a)(2)). In holding that the Secretary's refusal to bring suit was reviewable, this Court did not discuss the Secretary's contention that the decision was an unreviewable

exercise of prosecutorial discretion, but instead merely expressed agreement (421 U.S. at 567 n.7) with the court of appeals' treatment of the issue. See *Bachowski* v. *Brennan*, 502 F.2d 79 (3d Cir. 1974).

The court of appeals, in turn, had begun by noting numerous cases holding the exercise of enforcement discretion to be unreviewable (see 502 F.2d at 86-87), but the court distinguished the case before it on three grounds. First, the court concluded (*id.* at 87), based on the legislative history of the LMRDA, that in empowering the Secretary to bring suit to set aside an election, Congress intended the Secretary to act on behalf of aggrieved union members rather than merely on behalf of the public. Second, it noted (*id.* at 87-88) that union members have no remedy if the Secretary does not act. And third, the court observed (*id.* at 88) that the Secretary's discretion was restricted by statute because he was required to bring suit whenever there was probable cause to believe that there had been a violation affecting the outcome of the election and no settlement was reached.

None of these factors applies in the instant case. FDA enforcement is intended to protect the general public, not to redress individual wrongs; persons facing execution by lethal injection can challenge the legality of that method of capital punishment in other proceedings;[14] and under the FDCA, the FDA has

[14] The primary purpose of the Eighth Amendment is to proscribe "tortures" and other "barbarous" methods of punishment. *Gregg* v. *Georgia*, 428 U.S. 153, 170 (1976) (plurality opinion); *In re Kemmler*, 136 U.S. 436, 447-449 (1890) (holding electrocution not cruel and unusual method of execution); *Wilkerson* v. *Utah*, 99 U.S. 130, 136 (1879) (holding firing squad not cruel and unusual method of execution). Lethal injection statutes have been challenged under the Eighth Amendment on direct appeal from the judgment imposing the death sentence (see, *e.g.*, *Earvin* v. *State*, 582 S.W.2d 794, 799 (Tex. Crim. App.) (execution by lethal injection not cruel and unusual punishment)), cert. denied, 444 U.S. 919 (1979), and in habeas corpus proceedings (see, *e.g.*, *Ex parte Granviel*, 561 S.W.2d 503 (Tex. Crim. App. 1978) (execution by lethal injection not cruel and unusual punishment)).

the traditional broad scope of enforcement discretion. See 21 C.F.R. 10.45(d)(2)(i).[15] Thus, this Court's summary treatment of the issue in *Bachowski* provides no basis for departing from the well-established rule that prosecutorial and administrative enforcement decisions are generally not subject to judicial review.

B. The FDA's Decision Is Exempt From Review Because The Governing Statutes Do Not Limit The Agency's Discretion

Even if the presumption against judicial review of enforcement decisions is cast aside, there is still no basis for review in this case. As noted, agency action is exempt from review under the APA where the governing statutes do not impose standards restricting the agency's discretion. This case falls squarely within that exemption.

[15] 21 C.F.R. 10.45(d)(2) and (i) provides:

> (2) The Commissioner shall object to judicial review of a matter if:
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> (i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act * * *.

1. *The FDCA Does Not Limit The FDA's Enforcement Discretion.* It is perfectly clear that the FDCA provides no "law to apply" in this case. The provisions of the Act granting the FDA investigative and enforcement authority are "written in the language of permission and discretion." *Southern Ry.*, 442 U.S. at 455. The Secretary of Health and Human Services is expressly "authorized to conduct examinations and investigations for the purposes of [the FDCA]" (21 U.S.C. 372). The Secretary is also implicitly empowered to initiate civil actions to enjoin statutory violations (21 U.S.C. 332) and to condemn adulterated or misbranded foods, drugs, devices, and cosmetics (21 U.S.C. 334). However, no provision of the FDCA commands the FDA to initiate investigative or enforcement activity whenever a statutory violation is alleged or found.

Nor does the Act provide standards to be used by the FDA in determining whether or when to undertake such activity. "The statute is silent on what factors should guide the [agency's] decision; * * * on the face of the statute there is simply 'no law to apply' in determining if the decision is correct." *Southern Ry.*, 442 U.S. at 455.

The court of appeals made only the most perfunctory effort to show that the FDCA provides law to apply, although in our view that is the dispositive question in this case. The court of appeals observed in a footnote (Pet. App. 26a n.29) that provisions of the FDCA specify that violators "shall" receive specified penalties. The insubstantial nature of this argument was demonstrated by Judge Scalia's observation in dissent that "[m]ost of the criminal code is cast in such mandatory terms, and yet prosecutors' discretion not to indict is the archetype of unreviewable enforcement discretion" (Pet. App. 48a).[16]

[16] The court of appeals also relied (Pet. App. 26a n.29) on 21 U.S.C. 336, which provides that the Secretary of HHS is not required "to report for prosecution, or for the institution of libel or injunction proceedings, minor violations * * * whenever he believes that the public interest will be adequately served by a suitable written notice or warning." This provision does not impliedly require the FDA to take enforcement action whenever there is a violation that is not "minor." Insofar as respondents requested that the FDA take purely administrative action, the provision does not apply because it pertains only to the reference of cases to the Department of Justice for litigation. And insofar as respondents sought the initiation of litigation, the provision is equally inapplicable because the legislative history makes clear that it was not intended to alter the Justice Department's traditional prosecutorial discretion. See 83 Cong. Rec. 7792 (1938) (remarks of Rep. Lea) ("I call attention * * * to the fact that the mere circumstance that the Secretary does not report the offense does not excuse the accused from prosecution. The Attorney General may proceed in case he desires to do so."); *id.* at 7794 ("[T]here is nothing more common in the administration of justice than the exercise of the discretion of a prosecuting attorney where he knows it is impracticable to prosecute purely technical violations of the law."). Rather, the legislative history shows that the provision was intended to give statutory recognition to one aspect of the FDA's much broader enforcement discretion. During floor debate, it was noted that "there will be * * * thousands of technical violations of the food and drug law which cannot as a practical matter be prosecuted." 83 Cong. Rec. 7793 (1938) (remarks of Rep. Lea). The House Report stated (H.R. Rep. 2139, 75th Cong., 3d Sess. 5 (1938)) that 21 U.S.C. 336 gives "definite legislative sanction to the procedure."

It should also be noted that 21 U.S.C. 336 was enacted as a companion provision to 21 U.S.C. 335, which provides that the Secretary of HHS must give potential criminal defendants an opportunity for a hearing before referring a case to the Justice Department for prosecution. In light of this somewhat unusual provision, 21 U.S.C. 336 was designed simply to

2. *The Preamble To A Proposed But Unadopted Rule Does Not Limit The FDA's Enforcement Discretion.* Without any "law to apply" in the FDCA, the court of appeals turned to the preamble to a regulation that was proposed for notice and comment but was never adopted by the agency. See 37 Fed. Reg. 16503-16505 (1972). The entire weight of the court of appeals decision rests on this slender reed. The preamble, however, plainly does not provide a basis for judicial review.

a. In the first place, the preamble cannot fairly be read to restrict the agency's enforcement discretion. The subject of the preamble and the proposed regulation was not the FDA's exercise of enforcement discretion but a question regarding the interpretation of the FDCA's drug approval provisions. Specifically, the question addressed was the application of the drug approval provisions when approved drugs are prescribed by physicians for an unapproved use after shipment in interstate commerce. The preamble concluded that physicians are not prohibited from prescribing approved drugs for unapproved uses but that in certain circumstances the unapproved use of an approved drug may justify FDA enforcement ac-

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make clear that even if the Secretary finds after the hearing that there has been a "minor" or technical violation, the Secretary is not obligated to report the case to the Justice Department. See 83 Cong. Rec. 7792 (1938) (remarks of Rep. Lea) (discussing Sections 335 and 336 as interrelated provisions).

Respondents rely (Br. in Opp. 21) on provisions of the FDCA authorizing judicial review of various FDA regulations and orders. See 21 U.S.C. 346a(i), 348(g), 355(h), 360g. They also rely on 21 U.S.C. 332(a), which gives the district courts jurisdiction to restrain certain statutory violations. Obviously none of these statutes places the slightest restriction on FDA's enforcement discretion.

tion. The preamble was solely concerned with this question of statutory interpretation and did not purport to address the issue of the FDA's enforcement discretion.

The court of appeals, however, seized upon a single sentence in the preamble and wrenched it out of context.[17] The sentence stated (see Pet. App. 24a (emphasis added)) that "[w]here the unapproved use of an approved new drug becomes widespread or endangers the public health, *the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public.*" In context, this sentence meant only that, when a possible violation occurs, the FDA is obligated to fulfill its statutory mandate. But as previously observed, an agency may fulfill its statutory enforcement responsibilities by pursuing any of a number of enforcement strategies. An agency is not generally required to investigate or initiate enforcement action whenever a possible violation is reported or suspected. The FDA has always exercised the traditional broad scope of enforcement discretion. Indeed, its rules specify that the agency regards its enforcement discretion to be unreviewable. 21 C.F.R. 10.45(d)(2)(i). See page 25 note 15, *supra*. It is far-fetched to suggest that the sentence in the preamble was meant to surrender any portion of that discretion.

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[17] The court quoted (Pet. App. 24a, 25a) two other sentences from the preamble, but neither can possibly be read to limit the FDA's enforcement discretion. The first of these stated merely that the FDA would not "hesitate to take whatever action * * * may be required." The second stated that certain conduct constituted a statutory violation and "is punishable accordingly."

The wording of the preamble also refutes the suggestion that it was intended to limit the FDA's discretion. As Judge Scalia noted (Pet. App. 48a-49a), the sentence on which the court of appeals relied is full of flexible terms that do not provide a workable basis for judicial review. The sentence stated (see *id.* at 24a (emphasis added)) that "[w]here the unapproved use of an approved new drug becomes *widespread* or *endangers the public health*, the Food and Drug Administration is obligated to investigate it thoroughly and to take *whatever action is warranted* to protect the public." What is "widespread" use? What constitutes a sufficient danger to the public health? And in a given case, what action is "warranted"? It is evident that these questions cannot be answered intelligently without surveying the potential dangers posed by all the foods and drugs marketed in this country and all the resources at the FDA's command. We do not see how the courts could perform that function without taking over day-to-day operation of the agency.

Moreover, the preamble addressed only one small portion of the FDA's investigative and enforcement responsibilities: the unapproved use of approved drugs. This is an area in which the agency's authority to proceed is less well settled than in cases involving more common types of violations,[18] such as the promotion and sale of products for unproven uses. Neither the court of appeals nor respondents have suggested that the courts can review every FDA enforcement decision or even every decision involving the issue of misbranding. It is thus most unlikely that the FDA would have obligated itself to take in-

[18] See *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981).

vestigative or enforcement action in all cases in an area near the fringes of the law, while reserving the discretion not to proceed in cases where its authority is far more firmly established.

b. Even if the unadopted preamble had discussed the FDA's enforcement discretion, it would not bind the agency. Under most circumstances, of course, a rule that is proposed but not adopted has no legal effect. It cannot be judicially enforced any more than a bill that is not enacted into law.

The court of appeals justified its reliance on the preamble on two grounds. First, the court stated that the FDA itself considers the preamble to be "binding" and "authoritative" (Pet. App. 25a & n.28). Second, the court observed that the preamble fell within the APA's definition of a rule, which it construed as "broad enough to include nearly every statement an agency may make" (*id.* at 25a, quoting *Center for Auto Safety* v. *NHTSA*, 710 F.2d 842, 846 (D.C. Cir. 1983)). Neither of these grounds is valid.

The court of appeals' description of the status of the preamble in the FDA's eyes is misleading at best. Under the FDA's rules, a policy statement accompanying an unadopted regulation is considered to be an advisory opinion unless subsequently repudiated by the agency or overruled by a court. 21 C.F.R. 10.85(d).[19] Advisory opinions are usually requested

[19] 21 C.F.R. 10.85(d) provides in pertinent part:

> (d) A statement of policy or interpretation made in the following documents, unless subsequently repudiated

by persons who may be affected by FDA action. Advisory opinions bind the agency in the sense that the agency is usually precluded from taking action against a person or firm that has relied on such an opinion. See 21 C.F.R. 10.85(e).[20] However, the FDA's rules make clear that an advisory opinion does not establish legal standards or requirements that are binding in other contexts. The rules unequivocally state (21 C.F.R. 10.85(j) (emphasis added)):

> An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, *but not as a legal requirement.*

Accordingly, under its own rules, the FDA does not regard the unadopted preamble as a generally binding legal requirement.[21]

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by the agency or overruled by a court, will constitute an advisory opinion:

(1) Any portion of a Federal Register notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

[20] 21 C.F.R. 10.85(e) provides (emphasis added):

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked. *The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.*

[21] See *United States* v. *Articles of Drug* • • • *Promise Toothpaste*, No. 83-C-6129 (N.D. Ill. July 30, 1984), slip op. 11-15 (portions of unadopted preamble, particularly those

The other basis for the court of appeals' reliance on the preamble—that it falls within the APA's definition of a rule—is equally unsound. Assuming for the sake of argument that the preamble is a "rule" within the APA definition,[22] "as a matter of administrative law, • • • it seems clear that agencies are not required, at the risk of invalidation of their action, to follow all of their rules." *United States* v. *Caceres*, 440 U.S. 741, 754 n.18 (1979). Legislative rules [23] have the force and effect of law and thus gen-

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dealing with enforcement decisions, should not be regarded as advisory opinion; at most, advisory opinion restricts FDA authority to proceed against persons who have relied on opinion); *McIlwain* v. *Hayes*, 530 F. Supp. 973, 977-978 n.8 (D.D.C. 1981), aff'd, 690 F.2d 1041 (D.C. Cir. 1982).

[22] The APA's definition of a rule is broad and ambiguous. The APA states (5 U.S.C. 551(4)) that a "'rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement • • • law or policy." Whether an advisory opinion falls within the APA's definition of a rule is subject to dispute and may vary from case to case. See 2 K. Davis, *Administrative Law Treatise* § 7.4 (2d ed. 1979). Because the definition of a rule is so unclear, questions of administrative law can seldom be answered simply by applying that definition. As Professor Davis has observed, "[o]ften the best solution • • • is • • • to skip the labeling and to proceed directly to the problem at hand." K. Davis, *Administrative Law Text* § 5.01, at 123 (1972).

[23] "Legislative rules" have been defined as rules that are "'issued by an agency, pursuant to statutory authority and • • • implement the statute. • • • Such rules have the force and effect of law.'" *Batterton* v. *Francis*, 432 U.S. 416, 425 n.9 (1977) (quoting U.S. Dep't of Justice, *Attorney General's Manual on the APA* 30 n.3 (1947)). "Interpretative rules,"

erally bind an agency. *Vitarelli* v. *Seaton*, 359 U.S. 535 (1959); *Service* v. *Dulles*, 354 U.S. 363 (1957); 2 K. Davis, *Administrative Law Treatise* § 7.21 (2d ed. 1979). By contrast, interpretative rules and other agency pronouncements—guidelines, policy statements, advisory opinions, handbooks, manuals, instructions to staff—are generally not binding and thus do not furnish law to apply under 5 U.S.C. 701(a)(2). See, *e.g.*, *Schweiker* v. *Hansen*, 450 U.S. 785 (1981); *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 301-302 (1979); *Sullivan* v. *United States*, 348 U.S. 170, 173 (1954); *Gatter* v. *Nimmo*, 672 F.2d 343, 347 (3d Cir. 1982); *Pacific Gas & Electric Co.* v. *FPC*, 506 F.2d 33 (D.C. Cir. 1974); *Brennan* v. *Ace Hardware Corp.*, 495 F.2d 368, 376 (8th Cir. 1974); 2 K. Davis, *supra*, § 7.21, at 100. As Professor Davis has written (2 K. Davis, *supra*, § 7.21, at 105): "[w]hen a non-legislative rule explicitly states that it does not confer rights or impose obligations, the explicit statement should control in absence of a good reason to the contrary."

The unadopted preamble at issue here is certainly not a legislative rule,[24] and as previously shown, FDA regulations explicitly state that informal pronouncements such as the preamble do not impose generally binding legal requirements. 21 C.F.R. 10.85(j). Thus, in the absence of a good reason to the contrary —and there is none—the preamble should not be held to bind the agency.

Certainly this is not a case in which there has been detrimental reliance on the preamble.[25] Respondents make no claim that they relied on the preamble when they decided to commit their capital offenses. Moreover, judicial enforcement of the preamble would have highly undesirable practical consequences. As noted, the preamble is, at most, an informal statement of policy that the agency itself does not regard as binding except in narrow circumstances. The court of appeals' holding boils down to the proposition that any such agency statement regarding its enforcement policy provides a sufficient basis for judicial review of the agency's enforcement decisions. Adoption of this view would penalize an agency for explaining its enforcement policies to the public or for promulgating internal guidelines in an effort to ensure that its enforcement decisions are rational and consistent. Yet both of those activities are beneficial and should be encouraged.[26]

3. *The Question Whether There Is Law To Apply Does Not Depend Upon A Judicial Assessment Of "Pragmatic Considerations."* Since neither the FDCA nor the preamble provides any "law to apply" in this case, the only possible basis for the decision below is the court of appeals' conclusion (Pet. App. 24a) that

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which lack the force and effect of law, have been defined as "rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Ibid.* See also *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 302 n.31 (1979); 2 K. Davis, *supra*, § 7.8.

[24] Nor is this a case involving the extinguishment of rights that would otherwise have been available by statute. Compare *Morton* v. *Ruiz*, 415 U.S. 199, 236 (1974). Neither respondents nor any other member of the public ever had a statutory right to insist that the FDA pursue every possible case.

[25] See *United States* v. *Caceres*, 440 U.S. at 752-753 & n.15.

[26] See 2 K. Davis, *supra*, chs. 9, 10 (statements by enforcement officers concerning how enforcement discretion will be exercised are generally not binding).

"[t]he determination of whether there 'is law to apply' turns on such pragmatic considerations as whether judicial supervision is necessary to safeguard plaintiffs' interests, whether judicial review will unnecessarily impede the agency in effectively carrying out its congressionally assigned role, and whether the issues are appropriate for judicial review."[27] However, this test, which the court of appeals now regularly applies in cases in this area,[28] is not faithful to the restrictions on judicial review imposed by Congress.

The question whether a matter is "committed to agency discretion by law (5 U.S.C. 701(a)(2)) or whether there is "'law to apply'" (*Overton Park*, 401 U.S. at 410) is a straightforward question of statutory construction. It is not a policy question calling for judges to decide whether judicial supervision seems "necessary" or "appropriate" (Pet. App. 24a) based upon their "personal policy preferences" (*Chevron U.S.A. Inc.* v. *NRDC*, slip op. 27). As Judge Scalia aptly put it (Pet. App. 61a), the court of ap-

[27] The court did not "delve into a detailed analysis" of these considerations because it believed that the preamble provided "law to apply" (Pet. App. 24a).

[28] See *Falkowski* v. *EEOC*, 719 F.2d 470, 480 n.16 (D.C. Cir. 1983), petition for cert. pending, No. 83-2034; *Investment Co. Institute* v. *FDIC*, 728 F.2d at 526 & n.6 (majority of panel expresses "discomfort with the test" to which circuit is bound); *American Friends Service Committee* v. *Webster*, 720 F.2d 29, 39-45 & nn.10, 13 (D.C. Cir. 1983) (literal application of *Overton Park* test provides "limited guidance"; must be supplemented by "more pragmatic analysis"); *Local 1219, American Fed'n of Gov't Employees* v. *Donovan*, 683 F.2d 511, 515 (D.C. Cir. 1982); *Natural Resources Defense Council, Inc.* v. *SEC*, 606 F.2d 1031, 1044 (D.C. Cir. 1979).

peals' "pragmatic considerations" test means that the court is free to review discretionary administrative determinations whenever it "think[s] it a good idea." He added (*id.* at 61a-62a): "The recited 'pragmatic considerations' bear no rational relationship to 'whether there is law to apply.' One could with equivalent logic recite them as the definition of 'injury in fact'—or of almost any other concept that needs evisceration."

C. The Structure And Legislative History Of The FDCA Show That Congress Intended The FDA To Have Unreviewable Enforcement Discretion

Both the structure and legislative history of the FDCA reinforce the conclusion that the FDA was intended to have unreviewable enforcement discretion.

1. In *Southern Ry.*, this Court inferred from the structure of the Interstate Commerce Act that the ICC's enforcement decision was not reviewable. The Court relied upon the disruptive effect of permitting review: "If the Commission * * * must carefully analyze and explain its actions with regard to each component of each proposed schedule, and if it must increase the number of investigations it conducts, all in order to avoid judicial review and reversal, its workload would increase tremendously." 442 U.S. at 457. Similarly, court review of the FDA's enforcement decisions would seriously impair the agency's ability to carry out its congressionally assigned role.

The FDA's regulatory and enforcement duties are far reaching. The FDA bears either sole or primary regulatory responsibility for the safety of all of the nation's human and veterinary drugs, most foods, biological products (*e.g.*, vaccines and blood products), medical devices, and radiological products

(*e.g.*, X-ray machines, color television sets, and microwave ovens). The FDA implements its regulatory authority through both pre-marketing approval (which applies to most human and veterinary drugs, food additives, biological products, and certain medical devices) and extensive post-marketing enforcement programs, which consist primarily of scheduled inspections of manufacturing and holding facilities of all regulated products. Additionally, the FDA is the regulatory agency frequently called upon to deal with national emergencies such as the botulism scare of 1974 and, more recently, the Tylenol poisonings of 1983.

Enforcement of the FDA's regulatory authority takes place through seizures under 21 U.S.C. 334, injunctive actions under 21 U.S.C. 332, and criminal prosecutions under 21 U.S.C. 333. Administrative remedies are also widely utilized.

Judicial review of the FDA's myriad enforcement decisions would interfere greatly with these responsibilities. The court of appeals candidly admitted that review of such decisions requires a "searching and careful" scrutiny of "both the administrative record, particularly the uncontroverted evidence submitted by [respondents], and the agency's stated reasons for its action" (Pet. App. 31a). There is little doubt that such exacting review would pressure agencies to respond to requests for enforcement action with carefully phrased and factually detailed written decisions.[29] Agencies would be forced by the threat of

[29] Where agency action is subject to judicial review, this Court has frequently observed that "the orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed." *SEC* v. *Chenery Corp.*, 318 U.S. 80, 94 (1943); see also, *e.g.*, *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mutual*, No. 82-354 (June 24, 1983), slip op. 12-13; *FTC* v. *Sperry & Hutchinson Co.*, 405 U.S. 233, 249 (1972); *FPC* v. *United Gas Pipe Line Co.*, 393 U.S. 71, 73 (1968).

burdensome court proceedings and possible reversal to disclose sensitive and privileged information regarding their broad enforcement plans. They would also be compelled to expend resources that could be put to far better use. See L. Jaffe, *Judicial Control of Administrative Action* 272 (1965) ("Enforcement would become impossible if an agency were required to justify its prosecutorial choices.").

2. The legislative history of the FDCA also strongly supports the nonreviewability of the FDA's enforcement determinations. During Senate consideration of the bill that became the FDCA (S. 5, 75th Cong., 1st Sess. (1937)), Senator Moore observed (81 Cong. Rec. 2013-2014 (1937)) that doctors in his home state were "much concerned about the bill" (*id.* at 2014 (emphasis added)):

> *The doctors point out that * * * the provision as to prosecution is permissive; that it would not be necessary under the bill to enforce the law.* It would give the Secretary of Agriculture [30] the right to be judge, jury, and trial attorney. *He might or might not decide that he should present evidence of any violation to the proper authorities.*

Senator Moore was referring to a report of the Welfare Committee of the Medical Society of New Jersey, which was ordered printed in the Congres-

[30] Enforcement of the FDCA was originally the responsibility of the Secretary of Agriculture. Act of June 25, 1938, ch. 675, § 201(c) and (d), 52 Stat. 1041.

sional Record. The report stated (81 Cong. Rec. 2015 (1937)):

> The only part of the present S. 5 which is mandatory to the Secretary of Agriculture is chapter 3, Section 7, which requires the Secretary to hold hearings for "persons against whom proceedings are contemplated in accordance with regulation prescribed by himself" * * * * *.
>
> In the article by Dr. Woodward * * * he unequivocally condemned the discretionary features of the bill.

The report continued (81 Cong. Rec. 2016 (1937) (emphasis added)):

> Consider now the administrative features of S. 5 * * *. We find in section 25 of S. 5 [now 21 U.S.C. 372] that "The Secretary is merely authorized to conduct examinations and investigations for the purposes of this act." But this is not the worst, because in section 8 [now 21 U.S.C. 336] we find that the Secretary or his agent is given the right to simply write a letter to an offender for whatever he may say that he "believes" to be a "minor violation." A minor violation is legally undefinable in any court; a man's belief is equally undefinable in a statute * * *.
>
> Thus we find that this clause provides for an administrative arbitrator who may legally limit the definitions of offense and the infliction of penalty on each violation detected; *who may prosecute or withhold action as he sees fit*, and thus may adjudicate each offense en camera; a combination of legislative, administrative, and judicial functions in one Cabinet official, to be delegated to a bureau chief.

In his detailed response (81 Cong. Rec. 2016-2018 (1937)), Senator Copeland, the floor manager of the

bill, in no way contradicted this characterization of the bill. A substitute proposed by Senator Moore was defeated by the Senate (*id.* at 2018), and the FDCA passed the Senate soon thereafter (*id.* at 2019). On the House side as well, it was recognized that the FDA would have broad discretionary authority, like that of a criminal prosecutor, in determining whether to seek enforcement.[31] Congress thus clearly contemplated that the FDA would have no judicially cognizable duty to initiate proceedings to enforce the Act.[32] As a commentator wrote shortly after the

---

[31] Representative Lea, in connection with the section of the bill that became 21 U.S.C. 336, stated (83 Cong. Rec. 7793-7794 (1938)):

> [I]n this particular case we are dealing with the duties of a purely administrative official and this is far different from dealing with a judicial officer, even somewhat different from dealing with the Department of Justice. However, there is nothing more common in the practice of criminal law than for the prosecuting attorney to exercise his judgment as to the cases he will prosecute. * * *
>
> * * * * *
>
> [T]here is nothing more common in the administration of justice than the exercise of the discretion of a prosecuting attorney where he knows it is impracticable to prosecute purely technical violations of the law. This is a candid recognition of that practical situation, and I believe it will work for the betterment of law enforcement. * * *

[32] The legislative history on which the court of appeals relied (Pet. App. 26a n.29, citing S. Rep. 646, 74th Cong., 1st Sess. 10 (1935)) relates to statutory language that was never enacted and, in fact, was specifically rejected by Congress. Several years before the enactment of the FDCA, a predecessor bill was introduced. S. 5, 74th Cong., 2d Sess.

Act's passage: "Leaving aside the question of 'multiple seizures,' [33] the exercise of discretion by the federal authorities in determining whether to institute criminal or libel for condemnation proceedings or both is not subject to judicial interference." Lee, *The Enforcement Provisions of the Food, Drug, and Cosmetic Act*, 6 Law & Contemp. Probs. 70, 76 (1939).

(1936). As reported by the Senate committee, Section 702 of that bill contained the following language (S. 5, *supra*, at 23 (language marked out)):

> The district courts * * * are hereby vested with jurisdiction, on petition by any interested person, * * * to grant appropriate injunctive relief from any act or omission of any officer, representative, or employee of the Department in the administration of this Act, if it has been shown that such act or omission is unreasonable, arbitrary, or capricious, or not in accordance with the facts or law * * *.

The House committee omitted this language altogether, stating (H.R. Rep. 2755, 74th Cong., 2d Sess. 8 (1936)) that "[t]he committee was not aware of any precedent for such a proposition." See also Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, 1 Food Drug Cosm. L.J. 532, 564-565 (1946). The entire bill subsequently died because of a disagreement between the House and Senate over another issue. 80 Cong. Rec. 10514-10519, 10680 (1936); see Kleinfeld, *supra*, 1 Food Drug Cosm. L.J. at 566.

When a different Senate Bill 5 passed the 75th Congress to become the FDCA, the only express reference to review of the agency's refusal to act was the provision (now 21 U.S.C. 371(f)(1) and (3)) for court of appeals review of the Secretary's refusal to "issue, amend, or repeal" certain regulations —a limited provision clearly not applicable to the instant case.

[33] The FDCA limits the discretion of the FDA to *institute* a seizure proceeding for misbranding if another such proceeding is pending in any court based upon the same alleged misbranding. See 21 U.S.C. 334(a)(1). This limitation obviously does not affect the FDA's discretion not to institute proceedings.

II. EVEN IF REVIEWABLE, THE FDA'S ENFORCEMENT DECISION WAS RATIONAL AND SHOULD HAVE BEEN SUSTAINED

Even if the FDA's decision not to regulate the states' use of drugs in carrying out capital punishment were reviewable, it nonetheless should have been upheld. In those special circumstances in which judicial review of administrative enforcement decisions is allowed, the scope of review is limited to determining whether the agency has stated a rational basis for its decision. *Dunlop* v. *Bachowski*, 421 U.S. at 568, 572-573. That standard was easily met here.

A. The FDA Lacks Authority To Regulate The States' Use Of Lethal Injections For Capital Punishment

The FDA denied respondents' petition, first, because it concluded (Pet. App. 82a) that "the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction." An agency's interpretation of the statute it administers is entitled to considerable deference. As this Court recently noted (*Chevron U.S.A. Inc.* v. *NRDC*, No. 82-1005 (June 24, 1984), slip op. 4-5 (footnotes omitted)):

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Con-

> gress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Here, it certainly cannot be argued that "Congress has directly spoken to the precise question at issue." Neither the court of appeals nor respondents have produced a shred of evidence that Congress wanted the FDA to regulate the methods of capital punishment used by the states. Moreover, Congress's silence on this point cannot be attributed to the fact that no state employed lethal injections when the FDCA was enacted in 1938. The provisions of the FDCA upon which the court of appeals relied apply to all "drugs" and "devices." A "drug" is broadly defined to include any "articles (other than food) intended to affect the structure or any function of the body of man" (21 U.S.C. 321(g)(1)(C)). This definition arguably could encompass the cyanide tablets used in gas chambers. Likewise, a "device" is defined to include any "instrument, apparatus, implement, machine, contrivance * * * or other similar or related article * * * which is * * * intended to affect the structure or any function of the body of man" (21 U.S.C. 321(h) and (3)). The electric chair and gallows could also be argued to fall within this definition. In 1938, the state and federal governments regularly used these methods of capital punishment. Yet there is no indication that any member of Congress even considered the possibility that enactment of the FDCA might affect these practices.

Since Congress did not intend the FDA to regulate capital punishment, the remaining question is whether the FDA's construction of the statute is a permissible one. In this case, the FDA's interpretation is plainly correct. The statutory provisions upon which the court of appeals relied, 21 U.S.C. 331(k) and 352(f), prohibit the "misbranding" of drugs while they are "held for sale." Without exploring all of the elements needed to make these provisions applicable, it seems clear that Section 331(k) and 352(f) do not apply in the unique situation at issue here because the alleged act of misbranding does not occur while the drugs are "held for sale." It is true that the phrase "held for sale" has been given an expansive reading by the courts in the context of the FDA's traditional enforcement activity. See, *e.g.*, *United States* v. *Diapulse Corp.*, 514 F.2d 1097 (2d Cir.), cert. denied, 423 U.S. 838 (1975). However, there is no basis to apply it in a context so far afield from the FDA's traditional enforcement activity as the imposition of capital punishment. The court of appeals' and respondent's interpretation of this phrase is not supported by either the statutory language or a scintilla of evidence regarding Congress's intent.

According to respondents and the court of appeals, the misbranding takes place when the drugs are used by prison officials for a purpose (capital punishment) that is not listed on their labels.[34] See Pet. App. 16a-

[34] This case concerns the FDA's authority to regulate the states' *use* of drugs, lawfully in interstate commerce, for the unapproved purpose of causing death, and not the *marketing* of drugs for an unapproved use. If a manufacturer or anyone else in the chain of distribution directly or indirectly were to suggest that a drug may properly be used for an unapproved use, the Act would be violated. Thus, if a drug were marketed

17a. The court of appeals acknowledged (see *id.* at 14a) that the drugs are not "held for sale" in any literal sense when they are injected into the condemned prisoner against his will. But the court relied (*id.* at 14a-15a) upon legislative history showing that Section 331(k) was intended to exercise the full reach of federal power under the Commerce Clause for the purpose of protecting "consumers." We readily agree that Congress's purpose in enacting Section 331(k) was to extend the greatest possible protection to persons to whom drugs may be administered for conventional purposes. But, as noted, there is absolutely no evidence that Congress intended to regulate the use of drugs or devices, pursuant to a lawful court order, for the purpose of capital punishment. Unsupported by either the statutory language or any proof of congressional intent, the court of appeals' and respondents' strained interpretation of the statute must fail.[35] The "misbranding" provisions were not violated.

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for the purpose of causing death without being approved for that use, a violation would occur. In this case, however, it has not been alleged or shown that any manufacturer or distributor directly or indirectly promotes the use of the drugs at issue for the purpose of carrying out death sentences.

[35] In concluding that the FDA possessed the authority to grant respondents' requested relief, the court of appeals repeatedly referred to the FDA's actions regarding drugs used to destroy animals and drugs administered to prisoners participating in research projects. Pet. App. 11a-12a, 31a-32a. These situations, however, are clearly distinguishable. The FDA has special statutory authority in both of these areas. See 21 U.S.C. 355(i), 357(d), 360j(g) (research projects); 21 U.S.C. 360b(a)(1) (animal drugs). The FDA has asserted authority over the *marketing* of drugs to destroy animals. See *United States* v. *Beuthanasia-D Regular*, [1979 Transfer Binder] Food, Drug, Cosm. L. Rep. (CCH) ¶ 38, 265 (D. Neb.). And the drugs dispensed to prisoners in research

B. Other Legitimate And Substantial Considerations Support The FDA's Determination Not To Initiate Investigative Or Enforcement Activity

Even if the FDCA could somehow be stretched to reach the administration of lethal injections for purposes of capital punishment, the FDA properly exercised its "inherent discretion to decline to pursue certain enforcement matters" (Pet. App. 85a). In the first place, the FDA recognized that any efforts to assert jurisdiction would result in protracted and quite possibly unsuccessful litigation with the states.[36] See Pet. App. 32a, 82a-85a; *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981). It is certainly within an administrative agency's discretion to shun burdensome cases where its jurisdiction appears dubious at best.

The FDA had three additional sound reasons for its decision. To begin with, regulating the method of capital punishment used by the states, whether or not technically within the scope of the FDCA, is far removed from the FDA's central responsibilities. Surely the FDA acted reasonably in conserving its limited enforcement resources for matters more closely related to its principal mission.[37]

---

projects, participation in which is voluntary, are administered for conventional purposes and not for the purpose of punishment.

[36] Subsequent events have proven this prospect accurate. When a Texas prisoner sentenced to death by lethal injection obtained a district court injunction requiring the FDA to seize the State's drugs (*O'Bryan* v. *Heckler*, Civ. No. 84-996 (D.D.C. Mar. 30, 1984), vacated, No. 84-996 (D.C. Cir. Mar. 30, 1984), stay denied, No. A-791 (Mar. 30, 1984)), the State immediately sued the FDA to block the seizure. *McKaskle* v. *United States Food and Drug Administration*, No. H-84-1544 (S.D. Tex.).

[37] Respondents insist (Br. in Opp. 14 & n.8) that the FDA did not base its decision on the need to conserve its enforce-

The FDA's decision also was based upon appropriate respect for principles of federalism. The FDA stated (Pet. App. 82a) that its decision was "supported * * * by a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems." See also *id.* at 85a. Enacting laws to prevent and punish crime is among the most important powers of the states, and in prescribing lethal injection as the method of execution, the states acted within federal constitutional limits. The FDA was reasonable in deferring to the states' authority in this field.

Finally, the FDA acted reasonably in relying (Pet. App. 85a) in the alternative on the absence of a "serious danger to the public health." The court of appeals disagreed (*id.* at 5a), asserting that there was "a substantial threat of torturous pain to persons being executed." However, not only is the factual predicate for the court's conclusion dubious (see *id.* at 51a-52a & n.5), but the court appears entirely to have missed the point. The proper inquiry is not whether death by lethal injection involves pain but whether it involves more pain than death by alternative methods of execution, such as the electric chair, the firing squad, or the gas chamber. As Judge Scalia

---

ment resources for other endeavors. However, the FDA clearly and repeatedly invoked the well-known doctrine of prosecutorial discretion (see Pet. App. 85a), and one of the bases for that doctrine is the view that agencies must have the freedom to concentrate their enforcement resources in a manner that achieves optimum results. We do not believe that the FDA was obligated to spell out all the familiar grounds for this doctrine. Respondents' close parsing of the FDA's decision illustrates how burdensome it would be for agencies if their enforcement decisions were subject to judicial review.

put it (*id.* at 51a (emphasis in original)), "it is not a matter of pain versus no pain, but rather pain of one sort substituted for pain of another—*and in all likelihood substitution of a lesser pain, since that is the principal purpose of the lethal injection statutes.*" Such comparisons were made by the legislatures that enacted the lethal injection statutes. The FDA acted responsibly in declining to review their determinations on this unique subject.[38] Thus, even if the FDA's decision not to initiate enforcement proceedings were judicially reviewable, that decision was rational and should not have been disturbed.

---

[38] Contrary to respondents' suggestion (Br. in Opp. 23-24), the Supremacy Clause does not preclude the FDA from deferring to the states' considered judgment that lethal injection is the least painful method of capital punishment. State law cannot interfere with lawful FDA action, but the Supremacy Clause does not command the federal government to take enforcement action in every possible case.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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AUGUST 1984

APPENDIX

5 U.S.C. 701(a) provides in pertinent part:

> This chapter applies, according to the provisions thereof, except to the extent that—
>
> (1) statutes preclude judicial review; or
>
> (2) agency action is committed to agency discretion by law.

21 U.S.C. 331 provides in pertinent part:

> The following acts and the causing thereof are prohibited:
>
> * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

21 U.S.C. 352 provides in pertinent part:

> A drug or device shall be deemed to be misbranded—
>
> * * * * *
>
> (f) Directions for use and warnings on label
>
> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the

protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

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JOINT

APPENDIX

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CLERK

No. 83-1878

In the Supreme Court of the United States

OCTOBER TERM, 1983

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES,

Petitioner

v.

LARRY LEON CHANEY, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

JOINT APPENDIX

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PETITION FOR CERTIORARI FILED MAY 16, 1984
CERTIORARI GRANTED JUNE 18, 1984

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* The opinions of the district court and the court of appeals are printed in the appendices to the petition for writ of certiorari and have not been reproduced.

Civil Action No. 81-2265

LARRY LEON CHANEY, ALTON FRANKS, CARL MORGAN, CHARLES W. DAVIS, ROBYN PARKS, DOYLE SKILLERN, JERRY JOE BIRD, HENRY MARTINEZ PORTER, PLAINTIFFS

v.

RICHARD SCHWEIKER, as Secretary of Health and Human Services, DEFENDANTS

---

28 USC 1331(2); 1361; 2201

Complaint for declaratory and injunctive relief

DOCKET ENTRIES

DATE	NR.	PROCEEDINGS
1981		
Sept. 16	1	COMPLAINT; appearance; exhibits A-B.
Sept. 16		SUMMONS (3) issued.
Sep 30	2	AFFIDAVIT of Eileen Murray of service of summons and complaint upon U.S. Atty Gen and the deft on 9-21-81 by certified mail.
Sep 30	3	AFFIDAVIT of Willie Joyner of service of summons and complaint upon the U.S. Atty personally on 9-16-81.
Nov 16	4	ANSWER of deft to the complaint.
Nov 16		CALENDARED. C/D (N)

DATE	NR.	PROCEEDINGS
1981		
Nov 24	5	NOTICE to counsel setting a status conference on 12-4-81 @ 11:30 a.m. (N) PARKER, J.
Dec 4		STATUS CALL: Defts given until 12-14-81 to notify the Court or the Clerk's office if this case should be reassigned.
Dec 9		TRANSCRIPT OF PROCEEDINGS from 12-4-81; pages 1-13; (Rep: M. Eugene Olsen); court copy.
Dec 16	6	REASSIGNMENT Of civil case from Judge Parker to Judge Johnson.
1982		
Feb 22	7	APPEARANCE of Marcia A. Johnson as counsel for deft.
Mar 8	8	INTERROGATORIES (first set) of pltfs. to deft; exhibit A.
Mar 8	9	REQUESTS (first set) of pltfs for admissions to deft.
Mar. 9		STATUS CALL (Deft. to file motion to dismiss within 15 days) (Rep: Douglas MacQuown) JOHNSON, J.
Mar 18	10	MOTION of deft. to dismiss or, in the alternative, for summary judgment; statement of material facts; attachment; memo.
Apr 10	11	OBJECTIONS by deft to pltfs' first set of interrogatories.
Apr 10	12	OBJECTION by deft. to ptlfs' first set of request for admissions.
Apr 24	13	STIPULATION re: enlargement of time enlarging time until 4-14-82 for pltfs to respond to defts motion to dismiss or in the alternative for summary judgment, approved. (N) JOHNSON, J.

DATE	NR.	PROCEEDINGS
1982		
May 14	14	MOTION of pltfs for summary judgment; statement of material facts; memo in support of their motion for summary judgment and in opposition to deft's motion for summary judgment or in the alternative to dismiss; table of contents; table of authorities; exhibits A and B.
May 4	15	STIPULATION allowing deft until 5-14-82 to respond to pltfs' motion for summary judgment; approved. (N) JOHNSON, J.
May 14	16	MOTION of deft for an enlargement of time to oppose pltfs' motion for summary judgment.
May 19	17	REPLY MEMORANDUM of deft. in support of his motion to dismiss or for summary judgment and memorandum in opposition to pltfs' motion for summary judgment.
May 28	18	ORDER granting motion of deft for an extension of time to 5-18-82 to oppose motion for summary judgment. (N) JOHNSON, J.
Aug 18	19	APPEARANCE OF Jeffrey Gibbs as co-counsel for deft.
Aug 30	20	MEMORANDUM OPINION. (N) JOHNSON, J.
Aug 30	21	ORDER granting motion of deft in the alternative for summary judgment pursuant to FRCP 56(c); denying motion of pltfs for summary judgment; and dismissing this action with prejudice. (N) JOHNSON, J.
Oct 28	22	NOTICE OF APPEAL from order entered 8-30-82; $5.00 USDC fee and $65.00 USCA fee paid and credited to U.S. Treasury; copies sent to J. Gibbs and M. Johnson.

DATE	NR.	PROCEEDINGS
1982		
Oct 28		COPIES of notice of appeal and docket entries transmitted to USCA. USCA 82-2321.
Nov 8		RECORD ON APPEAL delivered to USCA. receipt acknowledged.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PARKER, J.

Civil Action No. 81-2265

LARRY LEON CHANEY, ALTON FRANKS,
CARL MORGAN, CHARLES W. DAVIS,
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DOYLE SKILLERN, JERRY JOE BIRD,
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v.

RICHARD SCHWEIKER, as Secretary
of Health and Human Services
200 Independence Avenue, S.W.
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DEFENDANT

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I

INTRODUCTION

1. This action arises out of the failure of a federal agency to perform its statutory duty to take steps to prevent the States of Oklahoma, Texas, Idaho and New Mexico from using drugs to execute prisoners when there is no evidence that these drugs will be safe and effective (that is, quick and painless), for this radically new, non-therapeutic and non-medical use. On December 19, 1980, the plaintiffs petitioned the Secretary of the Department of Health and Human Services to take certain steps, including the holding of evidentiary hearings, to enforce the Federal Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 301 *et seq.*, and to prevent this unapproved use of drugs. A copy of this petition is appended hereto as Exhibit A. Plaintiffs' petition alleged that there was in fact abundant evidence that the use of drugs for this purpose may actually result in the slow and painful deaths of condemned prisoners subjected to lethal injection. On July 7, 1981, the Secretary's agent, the Commissioner of the Food and Drug Administration, refused to take any of the action sought by plaintiffs' petition. A copy of the Commissioner's letter is appended hereto as Exhibit B. Plaintiffs therefore seek declaratory relief and an order compelling the Secretary of Health and Human Services to take the requisite steps to enforce the Act and prohibit this unapproved use of drugs.

II

PARTIES

A. *PLAINTIFFS*

2. Plaintiffs Larry Leon Chaney, Alton Franks, Carl Morgan, Charles W. Davis and Robyn Parks are inmates

at the Oklahoma State Penitentiary and are currently under sentence of death by lethal injection.

3. Plaintiffs Doyle Skillern, Jerry Joe Bird and Henry Martinez Porter are inmates at the Ellis Unit of the Texas Department of Corrections and are currently under sentence of death by lethal injection.

B. *DEFENDANT*

4. Defendant Richard Schweiker is Secretary of the United States Department of Health and Human Services and is sued in his official capacity as such. As Secretary of Health and Human Services, defendant Schweiker has the duty and responsibility to enforce the FDC Act.

III

JURISDICTION

5. Jurisdiction is vested in this Court pursuant to 28 U.S.C. § 1331(a) in that the matter in controversy arises under the laws of the United States and is brought against an officer of a United States agency in his official capacity.

6. Jurisdiction is also vested in this Court pursuant to the provisions of 28 U.S.C. § 1361, this being an action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to plaintiffs.

7. Pursuant to the provisions of Section 10 of the Administrative Procedure Act, 5 U.S.C. §§ 701-706, plaintiffs seek review of defendant Schweiker's denial of their petition. Through this denial, plaintiffs suffer legal wrong because of final agency action for which there is no other adequate remedy in a court, and they are adversely affected and aggrieved by agency action within the meaning of a relevant statute.

8. Pursuant to the provision of 28 U.S.C. § 2201, plaintiffs seek a declaration of defendant Schweiker's obligations under the FDC Act with respect to the regulation

of drugs used by the States in lethal injection executions and of plaintiffs' rights to be free from injection with drugs which are not safe and effective for their intended purpose as required by the FDC Act.

IV

STATEMENT OF CLAIM

9. Since 1977, four States—Oklahoma, Texas, Idaho and New Mexico—have enacted statutes mandating the use of drugs for a radically new purpose: the execution of human beings by lethal injection. Over 180 prisoners are now under sentences of death imposed pursuant to these statutes.

10. Oklahoma became the first State to adopt a lethal injection statute in 1977. The Oklahoma statute describes that State's method of execution by a lethal dose of drugs as follows:

> "The punishment of death must be inflicted by continuous, intravenous administration of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician according to accepted standards of medical practice."

Okla. Stat. Tit. 22, § 1014A. According to Oklahoma Department of Corrections Policy and Procedures Memorandum Number OP-050301 (Revised) issued July 21, 1981, the ultrashort-acting barbiturate to be used is sodium thiopental, while the chemical paralytic agent to be used is either tubocurarine, succinylcholine chloride or potassium chloride.

11. Abbott Laboratories, of North Chicago, Illinois, manufactures sodium thiopental. Eli Lilly and Company, of Indianapolis, Indiana, manufactures tubocurarine. Squibb & Sons, Inc., of Princeton, New Jersey, and Burroughs Wellcome Co., of Research Triangle Park, North Carolina, manufacture succinylcholine chloride. Invenex

Laboratories, of Orlando, Florida, manufactures potassium chloride. These drugs are manufactured for distribution and sale in interstate commerce.

12. The Texas lethal injection statutes, also adopted in 1977, provides that death shall be caused "by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death." Tex. Code Crim. Proc. Ann. Art. 43.14. According to the Texas Department of Corrections Procedures for the Execution of Inmates Sentenced to Death, the drug to be used in execution is sodium thiopental.

13. The Idaho statute, enacted in 1978, provides as follows:

> "The punishment of death must be inflicted by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death until the defendant is dead. The director of the department of corrections shall determine the substance or substances to be used and the procedures to be used in any execution."

Idaho Code § 19-2716. The Idaho Department of Corrections Death Penalty Procedures do not specify what the lethal drug will be.

14. The New Mexico execution statute, enacted in 1979, is similar to Oklahoma's statute:

> "The manner of inflicting punishment of death shall be by administration of a continuous, intravenous injection of a lethal quantity of an ultra-short-acting barbiturate in combination with a chemical paralytic agent."

N.M. Stat. § 31-14-11. There are no New Mexico Department of Corrections regulations designating the drugs to be used in an execution.

15. The FDC Act prohibits the interstate distribution of any "new drug" (including any previously known drug that is being used for a new purpose) unless the Secre-

tary of Health and Human Services has approved an application supported by substantial evidence of the drug's safety and effectiveness for its specified purpose. 21 U.S.C. § 355(a). The term "new drug" is defined by § 201(p)(1) of the FDC Act, 21 U.S.C. § 321(p)(1), to mean

> "Any drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, ..."

Under the FDC Act, general recognition of a drug's safety and effectiveness requires an "expert consensus" founded upon "substantial evidence," which the Act defines as:

> "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have. . . ."

21 U.S.C. § 355(d).

16. The Secretary, and his agent, the Commissioner of the Food and Drug Administration, have the statutory duty and responsibility of enforcing the FDC Act by, *inter alia*, promulgating regulations and holding hearings, 21 U.S.C. § 371, by conducting examinations and investigations, 21 U.S.C. § 372, by requiring record-keeping, 21 U.S.C. § 373, by making inspections, 21 U.S.C. § 374, and by issuing public reports, 21 U.S.C. § 375.

17. There is no evidence and no consensus in the scientific community that injection of the prescribed drugs will result in the quick and painless death of the condemned prisoner. Indeed, the only medical experts who have scientifically reviewed the humaneness and effectiveness of lethal injection, the British Association of Anesthetists and the British Medical Association, concluded that it did not present an acceptable alternative to traditional means of execution because quick and painless death was unlikely to result.

18. There is abundant evidence that the lethal injection authorized by the four State statutes is not a "safe and effective" (that is, quick and painless) means of executing human beings and that its use poses a substantial threat of torturous and unnecessary pain to persons being executed.

19. The American Medical Association and the professional medical societies of each of the four States with lethal injection statutes have all passed or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a lethal injection execution other than to make a determination or certification of death.

20. In both administrative and judicial proceedings, the Secretary and his agents have stringently enforced the FDC Act as applied to the regulation of drugs used by veterinarians to kill domestic animals, taking the position that such chemicals were "drugs" under the FDC Act for which new drug applications had to be filed demonstrating satisfaction of the FDC Act's requirements of safety and effectiveness.

21. The Secretary of Health and Human Services and his agents have not issued approvals for drugs to be used for the lethal injection of a human being.

22. Lethal injection involves the untested and unapproved use of drugs manufactured, distributed, and sold in interstate commerce to kill human beings and therefore violates the FDC Act.

23. On December 19, 1980, plaintiffs petitioned the Secretary of Health and Human Services pursuant to 21 C.F.R. § 10.30 to take certain steps to enforce the Act

and to prevent the unapproved use of drugs as a means of lethal injection. See Exhibit A, attached hereto.

24. Plaintiffs requested an evidentiary hearing on any controlling issue of fact raised by their petition. Exhibit A, at Page Nineteen.

25. Plaintiffs' petition contained a detailed recitation of the known evidence concerning lethal injection, which indicates that it is likely to cause slow and painful death in many cases. Plaintiffs appended to their petition three affidavits of leading medical and scientific experts (including the former president of the Florida Medical Association, and the Director of Anesthesiology at Boston's Peter Bent Brigham Hospital), which aver that there is no published scientific data or information respecting the safety and efficacy of lethal injection, that there are risks that intense pain may be caused in the administration of lethal drugs, and that there is a high likelihood that lethal injection may not produce speedy death.

26. Despite the Secretary's obligation under the FDC Act to prevent the harmful use of an approved drug in an unapproved manner, on July 7, 1981, the Secretary's agent, the Commissioner of the Food and Drug Administration, denied plaintiffs' petition without affording them an evidentiary hearing and refused to take any of the action sought by plaintiffs' petition. See Exhibit B, attached hereto.

27. The Commissioner's action in summarily rejecting plaintiffs' petition without consideration of any of the relevant evidence was unlawfully aribtrary, capricious, and an abuse of discretion. It was in disregard of the statute and failed to observe procedure required by law. It was unsupported by substantial evidence, and unwarranted by the facts to the extent that the facts are subject to trial *de novo* by this Court. It constitutes a plain failure to perform a legal duty owed to the plaintiffs. Plaintiffs and defendant are in actual controversy as to the interpretation of the FDC Act and defendant's duties under that Act in relation to the regulation of new drugs

to be used for the purpose of killing persons by lethal injection.

28. As set forth above, the actions of the defendant, except for the intervention of this Court and the granting of the relief prayed for herein, will cause plaintiffs irreparable injury for which they have no adequate remedy at law.

V

PRAYER

WHEREFORE, plaintiffs pray for a judgment declaring that the use of drugs by state departments of corrections for lethal injection presents a substantial question whether this practice violates the FDC Act and presents disputed factual issues that should be resolved in the first instance by the Food and Drug Administration. Plaintiffs also pray for an order requiring the Secretary of Health and Human Services to immediately hold evidentiary hearings, pursuant to the FDC Act, at which hearings plaintiffs may present relevant scientific and medical evidence, and to make detailed factual findings as to whether there is substantial evidence and an expert consensus that lethal injection, as administered in the States of Texas, Oklahoma, Idaho, and New Mexico is not violative of the FDC Act. The Secretary should be further required to consider whether any or all of the following steps may be necessary to prevent violations of the FDC Act:

(i) Affixation of a boxed warning to the labels of the drugs specified for use in a lethal injection execution in Oklahoma, Texas, Idaho and New Mexico that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

(ii) Distribution to the manufacturers of these drugs and to the departments of corrections in Oklahoma, Texas, Idaho and New Mexico of notices advising that the drugs specified in those States' execution statutes or prison policies for use in an execution are not approved for use as

a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

(iii) Placement in the Drug Bulletin of an article advising that the drugs specified for use in a lethal injection by statutes or prison policies in Oklahoma, Texas, Idaho and New Mexico are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

(iv) Adoption of a policy and procedure for the seizure and condemnation in prisons or State departments of corrections of drugs which are destined or held for use as a means of execution;

(v) Recommendation of the prosecution of manufacturers, wholesalers, retailers and pharmacists who knowingly sell drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess or use drugs for the unapproved use of lethal injections.

Respectfully submitted,

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Date: September 16, 1981

December 19, 1980

The Honorable Patricia Roberts Harris
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Harris:

During the last three years, four states—Texas, Oklahoma, Idaho and New Mexico—have enacted statutes mandating the use of specified drugs for a radically new purpose: the execution of human beings by "lethal injection." Prisons in these four states currently house 166 of the 691 persons under sentence of death in the United States. At least six other states—Florida, Tennessee, Nevada, South Carolina, Washington, and Kansas, which have a total of 186 death row inmates—have also seriously considered adopting some method of lethal injection.

Although the supporters of this new method of execution have advanced several pragmatic reasons for its adoption (for example, its inexpensive administrability,[1] its greater palatability to those who *witness* executions,[2]

[1] At the time Okahoma adopted its lethal injection statute, necessary repairs to the electric chair would have cost $62,000. An alternative option to build a gas chamber would have cost more than $200,000. The Oklahoma legislators were informed that death by injection would cost only $10 to $15 "per event." P. Malone, "Death Row and the Medical Model," Hastings Center Report p. 5 (October 1979).

[2] This rationale has become increasingly important recently as the number of potential witnesses to executions has increased. It is no coincidence, for example, that the Texas legislature passed its lethal injection statute shortly after a court held that executions in that state could be televised. Prior to passage of that statute, the laws of Texas mandated death by electrocution, which results in a visibly roasting skin, bulging eyeballs, bleeding nose and bursting bowels.

The effect on witnesses of a method of execution, of course, must be distinguished from its effect on the person being executed. For example, proponents of electrocution have long advanced the theory that, despite its gruesome aspect to witnesses, electrocution's effect on its victim is the instantaneous destruction of the nervous system, thereby precluding pain or any other sensation whatsoever.

and the possibility that it will increase the incidence of executions in this country[3]), they usually accompany these practical reasons with a totally unsubstantiated "humanitarian" argument of particular relevance to you in light of your responsibilities under the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. §§ 301 *et seq.*—*i.e.*, that the injection of drugs is a more humane and less painful means of executing people than the traditional methods[4] of electrocution, gas, hanging and shooting. In point of fact, lethal injection involves the use, by non-doctors, of drugs in an entirely new, non-therapeutic and non-medical fashion for which their safety and effectiveness have never been tested. In addition, there is strong evidence to believe that their use may actually result in agonizingly slow and painful deaths that are far more barbaric than those caused by the more traditional means of execution. In any event, there is absolutely no evidence, let alone a consensus in the scientific community, that the use of these drugs will result in the quick and painless death that their advocates claim.[5] Furthermore,

[3] Those advocates of lethal injection who are also strong advocates of capital punishment argue that since this method of execution is perceived by the public as more palatable, its adoption will decrease opposition to the death penalty, encourage judges and juries to sentence more people to death and discourage executive officials from commuting or failing quickly to carry out those sentences.

[4] Currently, the following means of execution are in force in the fifty states, Puerto Rico and the District of Columbia: electrocution (18); gas (10); hanging (5); lethal injection (4); shooting (1). Fourteen of these fifty-two jurisdictions do not have a death penalty.

[5] Indeed, the only medical experts who have considered the humaneness and effectiveness of "lethal injection" drugs, the British Association of Anesthetists, concluded that such drugs do

their manufacturers[6] have never applied to you for approval of this use of these drugs, nor, of course, have you granted such approval.

In a directly analogous case initiated by the Food and Drug Administration ("FDA"), a federal court in Nebraska last year ruled that drugs used by veterinarians to kill domestic animals were drugs under the Act and that their introduction into interstate commerce violated the Act since "new drug" applications had not been filed demonstrating that those drugs satisfy the Act's requirements of safety and effectiveness. *United States* v. *Beuthanasia D Regular*, CCH Food Drug Cosmetic Law Reports ¶ 38,265 (D. Neb. 1979). According to FDA Policy Guide No. 7125.17, September 15, 1977, products intended for animal euthanasia are drugs because they are intended to affect the function of the body by inducing death. The court expressly noted that relevant criteria in assessing the safety and effectiveness of such drugs included, *inter alia*, (1) the drug's ability to cause death without pain and discomfort; (2) the time required to produce loss of consciousness; (3) the time required to produce death; (4) the reliability of the drug to obtain consistently effective results. *Id.* at 39,129.

By way of this petition, therefore, the undersigned counsel, on behalf of Larry Leon Chaney, an inmate at the Oklahoma State Penitentiary, who is currently under sentence of death by lethal injection, and Doyle Skillern, an inmate at the Ellis Unit of the Texas Department of Corrections, who is currently under sentence of death by lethal injection, request that you take the steps delineated

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not present a viable alternative to traditional means of execution. See p. 9, n.9, *infra*.

[6] Abott Laboratories manufactures sodium thiopental. Eli Lilly and Company manufactures tubocurarine. Squibb & Sons, Inc. and Burroughs Wellcome Co. manufacture succinylcholine chloride. Invenex Laboratories manufactures potassium chloride. Physicians Desk Reference (34th Ed. 1980).

below to enforce the Act against the unapproved use of drugs for this unprecedented purpose of "lethal injection."

The Lethal Injection Statutes

Oklahoma became the first state to adopt a lethal injection statute in 1977. The Oklahoma statute describes that state's method of execution by a lethal dose of drugs as follows:

> "The punishment of death must be inflicted by continuous, intravenous administration of a lethal quantity of an ultrashort-acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician according to accepted standards of medical practice."

Okla. Stat. tit. 22, § 1014A. According to Oklahoma Department of Corrections Policy and Procedures Memorandum Number OP-090901 issued April 12, 1978, the ultrashort-acting barbiturate to be used is sodium thiopental, while the chemical paralytic agent to be used is either tubocurarine, succinylcholine chloride or potassium chloride.

The Texas lethal injection statute, also adopted in 1977, provides that death shall be caused "by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death." Tex. Code Crim. Proc. Ann. art. 43.14. According to the Texas Department of Corrections Procedures for the Execution of Inmates Sentenced to Death, the drug to be used in execution is sodium thiopental.

The Idaho statute, enacted in 1978, provides as follows:

> "The punishment of death must be inflicted by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death until the defendant is dead. The director of the department of corrections shall determine the substance or substances to be used and the procedures to be used in any execution."

Idaho Code § 19-2716. The Idaho Department of Corrections Death Penalty Procedures do not specify what the lethal drug will be.

The New Mexico execution statute, enacted in 1979, is similar to Oklahoma's statute:

> "The manner of inflicting punishment of death shall be by administration of a continuous, intravenous injection of a lethal quantity of an ultra-short-acting barbiturate in combination with a chemical paralytic agent."

N.M. Stat. § 31-14-11. There are no New Mexico Department of Corrections policy or procedure statements designating the drugs to be used in an execution.

The Department of Health and Human Services Has the Authority and Responsibility To Prevent the Use of Approved Drugs for the Unapproved Use of Lethal Injection

Lethal injection, the untested and unapproved use of drugs to kill people, violates the procedures of and the policies underlying the Federal Food, Drug and Cosmetic Act:

> "When a manufacturer or anyone in the chain of distribution suggests to a patient that an approved drug may properly be used for unapproved uses for which it is neither labelled nor publicly advertised, that action constitutes a violation of the act and is punishable accordingly as a misbranding of the drug. [Under Food and Drug Administration policy] a . . . person who ships or requests shipment of a prescription new drug in interstate commerce with the intent of applying it to an unapproved use . . . must first file with the Food and Drug Administration an investigational new drug plan as set out in 21 CFR, § 312.1."

United States v. *Evers*, 453 F. Supp. 1141, 1148 (M.D. Ala. 1978); *see also United States* v. *An Article of*

*Drug * * * Diso-Tate, Etc., H. Ray Evers, and Meadowbrook Hospital*, CCH Food Drug Cosmetic Law Reports ¶ 38,086 (E.D. La. 1976) (defendant lay person enjoined from using approved drug in unapproved fashion in direct contradiction to label). Furthermore, the FDA has emphatically stated that it will do all in its power to prevent the unapproved and dangerous use of approved drugs:

> "Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. Several alternative courses of action are available to the Food and Drug Administration under these circumstances, depending upon the specific facts of each case. These actions include: Requiring a change in the labeling to warn against or to approve the unapproved use, seeking substantial evidence to substantiate the use, *restricting the channel of distribution, and even withdrawing approval of the drug and removing it from the market in extreme cases. When necessary, the Food and Drug Administration will not hesitate to take whatever action of this nature may be required to bring possible harmful use of an approved drug under control.*
>
> * * * * *
>
> *Thus, where a manufacturer or his representative, or any person in the chain of distribution, does anything that directly or indirectly suggests to the physician or to the patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor advertised, that action constitutes a direct violation of the Act and is punishable accordingly.*"

37 Fed. Reg. 16504 (1972) (emphasis added.) The Act was held to apply to drugs used to kill animals last year.

Certainly the Act applies with no less stringency for drugs used to kill human beings.[7]

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[7] The Federal Food, Drug and Cosmetic Act prohibits the interstate distribution of any "new drug" (including any previously known drug that is being used for a new purpose) unless the Secretary of Health and Human Services has approved an application supported by substantial evidence of the drug's safety and effectiveness for its specified purpose. 21 U.S.C. § 355(a).

The term "new drug" is defined by § 201(p)(1) of the Act, 21 U.S.C. § 321(p)(1), to mean

> "Any drug . . . not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . ."

Although the Act does not define what constitutes general recognition of a drug's safety and effectiveness, the Supreme Court has interpreted this requirement to mean an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in the Act. *United States* v. *Rutherford*, 442 U.S. 544, 549-50 n.7 (1979). The Act defines "substantial evidence" as follows:

> "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have. . . ."

21 U.S.C. § 355(d).

The affdavits submitted by Drs. Vandam, Hodes and Casscells as part of this petition convincingly demonstrate that there is by no means an "expert consensus" founded upon "substantial evidence" consisting of "adequate and well-controlled investigations," including "clinical investigations," that the drugs to be used to execute people will have the effect they purport or are represented to have, to wit, that they will produce loss of consciousness and death quickly and without pain and discomfort. These experts are not aware of any published scientific data or information which in any respect addresses the use of these drugs as a means of execution, much less establishes their effectiveness. Nor are these experts aware of any adequate and well-controlled investigations establishing the effectiveness of these drugs for a lethal injection.

Thus, to the extent that the manufacturers or anyone in the chain of distribution of sodium thiopental, tubocurarine, succinylcholine chloride and potassium chloride promote the use of these drugs for the unapproved use of lethal injections, a violation of the Act occurs and the Department of Health and Human Services should take appropriate action to end such violations.

There is Strong Evidence That the Lethal Injection of Drugs Is Not A "Safe and Effective" Means of Executing People and That Its Use Poses A Substantial Threat of Torturous Pain to Persons Being Executed

According to Dr. Richard S. Hodes and Dr. Leroy Vandam, both of whom are accomplished anesthesiologists familiar with the drugs specified for use in a lethal injection as well as with the "intravenous" injection procedure mandated in all four lethal injection statutes and their interpreting regulations,[8] those drugs and that procedure may well not produce a quick, painless death. In particular, intravenous injection of drugs is a delicate and skilled operation which requires professional expertise. Even when performed by an expert, the process of intravenous injection and the determination of the dosage to be injected are always subject to substantial technical difficulty, which may result in the infliction on the recipient of severe physical and mental pain. For these reasons, the British Association of Anesthetists and the British Medical Association disapproved of lethal injections in reports to the Royal Commission on Capital Punishment, which Commission, in turn, recommended to Parliament that it not adopt lethal injection as a means of execution.[9]

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[8] Dr. Hodes is former president of the Florida Medical Association. Dr. Vandam is Professor of Anesthesia, Emeritus, at Harvard Medical School, Anesthesiologist to Boston's Peter Bent Brigham Hospital and Director of Anesthesiology at Boston's Hospital at Parker Hill, a hospital run by the Harvard Community Health Plan. Curricula vitae for both Dr. Hodes and Dr. Vandam are attached to their affidavits.

[9] According to the Report of the Royal Commission on Capital Punishment presented to the English Parliment in 1953 (Exhibit

There are at least four separate reasons why the intravenous injection of drugs is an unsafe, ineffective and inhumane means of executing people even when administered by expert medical practitioners:

First, it is extremely difficult if not impossible, to give intravenous injections to persons with certain physical conditions and abnormalities. Specifically, it is difficult to locate and enter veins in the obese, in persons with heavily pigmented skin, in drug addicts where veins may be thrombosed as the result of prior drug injections, in the elderly with fragile veins, and in persons with a history of diabetes, uremia and other conditions. Given the high percentage of black and other minority inmates on death row,[10] and the disproportionately high incidence in

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1), the British Association of Anesthetists rejected lethal injection as impracticable for three reasons:

> "First, it is impossible to give an intravenous injection to anyone with certain physical abnormalities. Secondly, it is never easy to give one except with the cooperation of the subject. Thirdly, the operation demands professional skill, which the medical profession would be unwilling to use for such purpose."

Report, Royal Commission on Capital Punishment 1949-1953, p. 258 (September 1953). The British Medical Association also rejected lethal injection: "the practical difficulties encountered in many cases when injection into a vein is attempted are such as to render the method quite unsuitable for the purpose of execution." *Id.* The Report also notes that the prison medical officers interviewed by the Commission were of the opinion that lethal injection was no more humane than hanging. *Id.* at 257.

[10] Three hundred twenty-two (322) of the 691 prisoners currently on death row in this country are black or members of another minority group. The President's Commission on Law Enforcement and Administration of Justice concluded that "there is evidence that the imposition of the death sentence and the exercise of dispensing power by the courts and the executive follow discriminatory patterns. The death sentence is disproportionately imposed and carried out on the poor, the Negro, and the members of unpopular groups." The Challenge of Crime in a Free Society, a Report by the President's Commission on Law Enforcement and Administration of Justice 143 (1967).

Less than two months ago, the Supreme Judicial Court of Massachusetts in *District Attorney* v. *Watson*, —— Mass.——, 411 N.E.2d

minorities of these physical conditions and abnormalities associated with difficult intravenous injection,[11] the difficulty of intravenous injection would be a problem which would present itself with substantial frequency in administering lethal injections.

In addition, the average person, when faced with the typically fearful prospect of an intravenous injection, experiences the constriction of veins as a result of sympathetic nervous activity, *i.e.*, the release of adrenalin. Given the uniquely horrible consequences of a *lethal* in-

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1274 (October 28, 1980), ruled that the death penalty violates the prohibition against cruel or unusual punishment contained in article 26 of that State's Declaration of Rights for two reasons: it is unacceptably cruel under contemporary standards of decency and it is administered with unconstitutional arbitrariness and racial discrimination. The court cited data from 1972 through 1977 to show that the death penalty was arbitrarily and discriminatorily administered against blacks:

> "In Florida, of 286 blacks who had killed whites, forty-eight (16.8%) were sentenced to death; of 111 whites who killed blacks, none were sentenced to death. In Georgia, of 258 blacks who killed whites, thirty-seven (14.3%) were sentenced to death; of seventy-one whites who killed blacks, two (2.8%) were sentenced to death. In Texas, of 344 blacks who killed whites, twenty-seven (7.8%) were sentenced to death; of 143 whites who killed blacks, none were sentenced to death. . . .
>
> "[In] Ohio . . . of 173 black persons who killed white persons, thirty-seven of them (21.4%) were sentenced to death. Of forty-seven whites who killed blacks, none were sentenced to death."

411 N.E.2d at 1285-86. (emphasis in original).

[11] Obviously, the incidence of heavy skin pigmentation is much higher among blacks and other minorities. However, the same is true of many of the other physical characteristics associated with difficulty in administering an intravenous injection. For example, minorities are significantly more likely to suffer from diabetes, and twice as likely to die from that malady, than whites. Similarly, the incidence of abuse of intravenously injected drugs is much higher among minorities than among whites. U.S. Department of Health, Education and Welfare, Health Status of Minorities and Low-Income Groups, at 106, 125-26, 180-81 (1979).

jection of drugs, it is highly probable that in the moments before his or her scheduled execution a death row inmate's veins would become constricted, thereby increasing the difficulty of performing an intravenous injection. Furthermore, an intravenous injection is considerably more difficult and unreliable in a resisting individual, a likely possibility given the circumstances of a lethal injection.

Under any of the circumstances discussed above, intravenous injection might result in painfully repeated but very possibly unsuccessful efforts to "find" a vein, or in the injection of the drug into either the tissues surrounding the vein or into an artery, the excruciating consequences of which are discussed below.

Second, insertion of a needle into a vein is always painful, even if a local anesthetic is first used. Repeated attempts at finding a vein cause additional pain and result in the escape of blood into the surrounding tissues, causing painful swelling and occlusion of other veins.

Third, even if the needle appears to be within a vein, the drug nevertheless might escape into the surrounding tissues upon injection, causing severe pain and swelling. This would be especially likely to occur in persons with flat veins which make it impossible to prevent the needle, which has pierced one wall of the vein, from going through the opposite wall as well. Sodium thiopental is a highly alkaline solution (ph 11.5) which causes local thrombosis of the vein in some people. Given the nature of the drugs used in lethal injections, the result of this subcutaneous administration would be highly painful. For example, if sodium thiopental accidently enters tissue, painful neuritis occurs if a nerve is adjacent. The same results occur with potassium chloride and acidic solutions such as succinylcholine and tubocurarine.

Because of the difficulty in performing an intravenous injection, it is also very possible to inject the drug mistakenly into an artery causing the artery to constrict and the surrounding tissue to die, often with extensive gangrene, and always with excruciating pain to the receipient. As a result of the drug escaping into the surrounding tissues or entering an artery, moreover, the injected drug would fail to produce its intended result.

Fourth, determining the proper dosage of drugs to be used in a lethal injection would be an extremely difficult task. Response to a set dosage varies from person to person depending upon several factors including age, body mass, physical condition and current as well as prior use of other drugs. It is likely, for example, that a drug addict or alcoholic would need more than a normal dosage. Furthermore, some people are born with genetic responses to drugs which might also influence dosage.

When used for such therapeutic purposes as anesthesia, thiopental, tubocurarine and other lethal injection drugs are given intermittently in measured amounts until the desired effect is achieved. Even in a well-controlled hospital setting, however, it is not very unusual for a patient to experience pain or to recall operative events when presumably asleep. In the tension-packed setting of an execution, the results could be excruciating. If in administering death by injection of drugs an insufficient amount of thiopental were administered, for example, followed by tubocurarine or some other paralytic agent, the recipient could awaken paralyzed and unable to breathe, with the result that he or she would die an excruciatingly slow death in conscious physical and mental agony. This might also occur if the thiopental escaped into the surrounding tissue upon injection or were accidentally injected into an artery.

Thus, the successful administration of a painless lethal injection and the determination of the correct dosage of drugs to be used would be very difficult even for the most highly trained and experienced of physicians. In practice, however, the risks of improper administration or determination of dosage in the context of lethal injections would be substantially greater because highly trained expert physicians and other health professionals will not—

indeed, legally and ethically *cannot*—participate in such activity.

Participation of a physician in an execution by lethal injection, be it through the ordering of the drugs, the preparation of the dosage, the actual administration of the injection or the supervision of others in carrying out these tasks, would be a violation of the physicians' Hippocratic Oath, the ethical guide of the medical profession for 2500 years, which provides:

> "To please no one will I prescribe a deadly drug, nor give advice which may cause his death." [12]

The American Medical Association ("AMA") and the professional medical societies of each of the four states with lethal injection statutes have all passed or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a legally authorized execution other than to make a determination or certification of death.[13]

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[12] *Dorland's Illustrated Medical Dictionary* (24th Ed. 1965).

[13] On July 22, 1980, the American Medical Association's governing body, the House of Delegates, adopted the following recommendation of the AMA Judicial Council:

> 'A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution."

The Oklahoma Medical Association is a "unified" professional society, which means that all members of the Oklahoma Medical Association are also members of the AMA and must therefore follow its guidelines.

On August 2, 1980, the Council of the New Mexico Medical Society endorsed the recently adopted AMA position.

Similarly, on July 26, 1980, the Idaho Medical Association's House of Delegates adopted a resolution advising its members not to participate in executions by administration of a lethal substance because "it is contrary to medical ethics for a physician to take a human life under any circumstances." The Idaho Medical Association formally stated that "a physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

On May 11, 1977, immediately following passage of the Texas lethal injection statute, the Texas Medical Association Board of

The condemnation by the various medical societies of physicians' medical participation in the preparation, administration or supervision of a lethal injection is consistent with the views articulated by Dr. William J. Curran of Harvard Medical School and Dr. Ward Casscells, co-authors of "The Ethics of Medical Participation in

---

Councilors declared that a physician, by virtue of the Hippocratic Oath, cannot take a life under any circumstances. The Board unanimously agreed to adopt the following opinion:

> "A physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

This position was reaffirmed by the Board of Councilors in May, 1980.

Similarly, on June 20, 1980, the Board of Trustees of the American Psychiatric Association ("APA") approved the following statement:

> "The physician's serving the state as an executioner, either directly or indirectly, is a perversion of medical ethics and of his or her role as healer and comforter. "APA therefore strongly opposes any participation by psychiatrists in capital punishment, that is, in activities leading directly or indirectly to the death of a condemned person as a legitimate medical procedure."

137 Am.J. Pschiatry 1487 (November 1980).

It is likely that many if not most physicians would refuse to be present at a lethal injection even for the sole purpose of certifying death. According to Dr. Ward Casscells and Dr. William Curran, it is ethically improper for a physician to be present and performing a monitoring role at a lethal injection:

> "It is similar to the physician who examines the prisoner intermittently during torture or prolonged interrogation and pronounces him physically fit to continue his ordeal. The 'continuous intravenous injection' ends only when the monitoring physician pronounces the condemned prisoner dead. The physician then becomes the instrument, the order, to stop the lethal action itself. There is no other way to describe this physician's role but as that of an active participant, a key human participant, in the execution."

See "The Ethics of Medical Participation In Capital Punishment By Intravenous Injection," The New England Journal of Medicine 226,229 (Jan. 24, 1980), Attachment 1 to Dr. Casscell's Affidavit at p. 4.

Capital Punishment by Intravenous Drug Injection" published in the January 24, 1980 edition of The New England Journal of Medicine. In this article, Dr. Curran and Dr. Casscells forcefully express the view that a physician's preparation, administration or supervision of a lethal injection is a violation of ethical principles of the medical profession and a

> "perversion of biomedical knowledge and skill for a nonmedical purpose. It would, in our judgment, violate the medical practice act of any American jurisdiction."

(Attachment 1 to Dr. Casscell's Affidavit at p. 4.)

In addition to being contrary to the traditional Hippocratic Oath, a physician's participation in a lethal injection would be in violation of the World Medical Association's Declaration of Geneva, the modern version of the oath, which provides "even under threat, I will not use my medical knowledge contrary to the laws of humanity." This Declaration was adopted in 1948 in response to the atrocities committed by medical personnel in Nazi Germany. The defense of Nazi physicians that they were following orders was rejected as a violation of the moral imperative to refuse to kill or to harm the prisoners or to take part in atrocities in any way.[14]

The licensing laws and ethical standards for nurses and medical technicians would also prevent them from carrying out a lethal injection. This is so not only because all health professionals adhere to their own versions of the Hippocratic Oath, but also because such personnel do not have the authority to prepare or administer a drug dosage independent of a physician's specific order or valid standing orders, which orders, of course, could not ethically or legally be forthcoming from doctors. Furthermore, such personnel would be even less experienced than physicians in carrying out drug injections since they would be less likely to have worked with laboratory animals.

The ethical principles which prohibit physicians from participating in a lethal injection would also make it improper for physicians to train any other person to perform lethal injections, assuming even that physicians possessed the skills and knowledge to provide the training. Of course, physicians are not trained to prepare lethal "medications" for human administration, and few, if any, physicians would have experience in administering poison or medication overdoses continuously to the point of death.

[14] Nazi Germany has not been the only time and place where physicians have disregarded their moral obligation and turned their knowledge of the healing arts to torture and death. Other chilling examples have been described by Solzhenitsyn in Stalinist Russia and by Amnesty International in Chile, Iran, Paraguay, Portugal and Argentina. See "The Ethics of Medical Participation in Capital Punishment By Intravenous Injection," The New England Journal of Medicine 226, 227-28 (Jan. 24, 1980), Attachment 1 to Dr. Cassell's Affidavit at pp. 2-3. These examples are clearly extreme, but they explain why the American medical societies have unanimously rejected physicians' participation in lethal injections as the state's executioner.

The Department of Health and Human Services Should Exercise Its Statutory Authority and Responsibility To Enforce the Act Against the Unapproved Use of Lethal Injection Drugs

To date, no person has been put to death by an injection of a lethal dose of drugs. The day is fast approaching, however, when the final appeals of prisoners on death row in Texas, Oklahoma, Idaho or New Mexico will be exhausted. Under an unsubstantiated medical veneer of humanity and decency, the first execution by means of a drug poses a real threat of leading to society's widespread but misguided acceptance of lethal injection as a cheap and deceptively palatable way of performing executions. Before this occurs, the time should be taken by your Department, pursuant to its statutory responsibility, to step back and analyze what is in fact taking place: the use of untested drugs to kill people, adminis-

tered not by trained physicians or other health professionals in their practice of medicine, but by untrained, nonprofessional personnel.

Therefore, pursuant to the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, on behalf of Larry Leon Chaney and Doyle Skillern, death row prisoners in Oklahoma and Texas who are currently under sentences of death by lethal injection, we hereby request by means of this petition filed pursuant to 21 C.F.R. § 10.30 that you take the following steps:

1. Affix a boxed warning to the labels of the drugs specified for use in a lethal injection by statutes or prison policies in Texas, Oklahoma, Idaho and New Mexico that these drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

2. Prepare and send to the manufacturers of the drugs and to prisons and departments of corrections in Texas, Oklahoma, Idaho and New Mexico (see Exhibit 2) notices advising that the drugs specified in those states' execution statutes or prison policies for use in an execution as well as any other drug or drugs are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

3. Place in the Drug Bulletin an article advising that the drugs specified for use in a lethal injection by statutes or prison policies in Texas, Oklahoma, Idaho and New Mexico are not approved for use as a means of execution, are not considered safe and effective as a means of execution, and should not be used as a means of execution;

4. Adopt a policy and procedure for the seizure and condemnation from prisons or state departments of corrections of drugs which are destined or held for use as a means of execution;

5. Recommend the prosecution of manufacturers, wholesalers, retailers and pharmacists who knowingly sell

drugs for the unapproved use of lethal injection and prison officials who knowingly buy, possess or use drugs for the unapproved use of lethal injections.

If after reviewing this petition you would like additional information or clarification of the matters presented, we would be happy to meet with you to discuss the issues raised by this petition. Furthermore, petitioners request a hearing on any controlling issue of fact raised by this petition.

We look forward to your prompt response to this petition.[15]

---

[15] The undersigned certify, that, to the best of their knowledge and belief, this petition includes all data, information, and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Since this petition does not request agency action significantly affecting the quality of the human environment, an environmental impact statement is not required. 21 C.F.R. § 25.1.

Sincerely,

/s/ Stephen M. Kristovich
DAVID E. KENDALL
STEPHEN M. KRISTOVICH
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Washington, D.C. 20006
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Dr. Stuart Nightingale
Dr. J. Richard Crout
Nancy Buc, Esquire
Michael Peskoe, Esquire
Hearing Clerk, FDA

EXHIBIT 1

[EMBLEM]

ROYAL COMMISSION ON CAPITAL PUNISHMENT 1949-1953 REPORT

Presented to Parlament by Command of Her Majesty
September 1953

LONDON
HER MAJESTY'S STATIONERY OFFICE
Reprinted 1973

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New methods of execution

735. We have pursued our inquiry into the question whether there is any other method, as yet untried, that could be relied on to inflict death as painlessly and certainly as hanging but with greater decency, and without the degrading and barbarous associations with which hanging is tainted. Only two suggestions were made to us deserving serious consideration.[8] One is the use of lethal gas in a way that does not need a gas-chamber. The other is execution by means of a hypodermic injection of a lethal drug.

736. *Lethal gas without a gas-chamber.* Our rejection of the existing method of execution by lethal gas was based in part on its employment of the elaborate contrivance of a gas-chamber. We thought it right therefore to consider the possibilities of execution by lethal gas administered in some other way. We were impressed by the opinion of the British Medical Association that if an alternative to hanging had to be found (though they did not advocate any change) gassing by carbon monoxide would be best. "A concentration of pure and odourless carbon monoxide", they said, "would cause loss of consciousness instantaneously and painlessly, followed rapidly by death."[9] But they recognised that what they called the "highly unpleasant historical associations" of gassing might rule out all variants of that method. In making their suggestion they had in mind the use of a gas-chamber, but we later discussed with other medical witnesses whether it would be practicable to dispense with one, and to administer the gas through a mask. Several objections to this were pointed out. It was said that the

[8] We have not thought it necessary to consider seriously the alternative of execution by some such weapon as a "humane killer"; we are sure that any such method would be abhorrent to public opinion.

[9] p. 318 (31).

prisoner would not become unconscious for at least a minute after the first inhalation of the gas, and the interval would probably be longer because no one so treated could help holding his breath as long as possible: that forcibly to apply a mask to a conscious man would be to invite struggling, involuntary perhaps and certainly ineffective, but distressing and unseemly; that disagreeable incidents like these could only be avoided by making the prisoner unconscious first, and that if he were unconscious there would be no point in using gas; he would be despatched more simply and decently by a lethal injection. We find the objections conclusive.

737. *Lethal injection.* A lethal injection from a hypodermic syringe has not, so far as we know, been adopted anywhere as a method of judicial execution. But to those who accept our postulate that the only requisites are humanity, certainty and decency this is likely to be the alternative to hanging that first suggests itself. We discussed it with representatives of the British Medical Association and later in some detail with members of the Association of Anaesthetists who were good enough to give us the benefit of their special knowledge of the subject.

738. As is well known, injections commonly given in medical practice are of two kinds, intramuscular and intravenous. An intramuscular injection needs no special skill; anyone can learn to give one in a few minutes. An intravenous injection is a delicate and skilled operation. A lethal dose can be given either way, but only if it is given intravenously can it be certain that death will be both quick and painless. We shall therefore consider this method first. The drug, probably a barbiturate, such as hexobarbitone or thiopentone, would be injected into a vein, preferably at the bend of the elbow or the wrist. In about twenty or thirty seconds, perhaps before the dose was completed, the drug would reach the brain. The prisoner would then become unconscious and die a minute or two later. There would be no danger of failure if a large

enough dose were given, and the prisoner would feel nothing after the prick of the needle. Except for the application of some form of restraint to prevent movement, the only preparation he would have to undergo would be the tying of a tourniquet round his arm, though it would be necessary, some time before the execution, to inspect his veins to make sure that the operation was unlikely to be impeded by any physical abnormality.

739. It appears then that intravenous injection, if practicable, would fulfil our three requisites better than any other method. But our expert witnesses questioned its practicability. The prison medical officers doubted even whether it was more humane than hanging:

> "2373. (*Chairman*) What are the objections that you see to a lethal injection?—(*Dr. Landers*) We do not think it would be any more humane, and we think the main objection is its impracticability.
>
> 2374. Would you enlarge on that——?—It raises the question as to who is to do it, and how they are to do it. We cannot suggest who is to do it. We can think of ways it could be done, but looking at it from a wide angle we doubt if it would be any more expeditious than hanging.
>
> 2375. Anyway, you have fully considered that, and you have rejected any other method in favour of hanging, which you think is the best form of execution?—Yes".

The opinion of the British Medical Association[1] was:

> "If it were practicable, the intravenous injection of a lethal dose of a narcotic drug would be a speedy and merciful procedure . . . But the practical difficulties encountered in many cases when injection into a vein is attempted are such as to render the method quite unsuitable for the purpose of execution".

[1] p. 318 (29).

740. Later, with members of the Association of Anaesthetists, we went into the reasons why the method was called impracticable. Substantially they are three. First, it is impossible to give an intravenous injection to anyone with certain physical abnormalities. Secondly, it is never easy to give one except with the co-operation of the subject. Thirdly, the operation demands professional skill, which the medical profession would be unwilling to use for such a purpose.

741. As to the first of these, we were told that in some people the veins are so covered with layers of fat as to be invisible, and in others they are so flat that it is almost impossible to prevent a needle which has pierced one wall from going through the opposite one as well. These conditions are rare: it is estimated that, with a willing subject, abnormal physical characteristics on this sort might make venepuncture difficult in one in five hundred cases and impossible in one in three thousand. There is, however, the further difficulty that even normal veins may become flattened by cold or nervousness, a condition not improbable in the circumstances we have to envisage. The usual way of restoring the veins is to immerse the arm in hot water until they become rounded, a process that may take ten to fifteen minutes, and even then several attempts may be necessary before an injection can be successfully given.

742. As to the second, intravenous injection is so delicate an operation that it cannot be done quickly and certainly unless the subject keeps absolutely still. Even with the arm strapped to a splint, this may not be easy to secure with an unwilling subject.

> "A vein is not like an artery, which has a fairly thick wall. It has a very thin wall, and the moment you touch a vein with a needle the two sides tend to go together, and therefore any movement will tend to let your needle go through both walls, or one side or

the other, and even the slightest movement will deflect your needle".[2]

743. The third reason for holding this method to be impracticable was put thus by the British Medical Association:[3]

> "No medical practitioner should be asked to take part in bringing about the death of a convicted murderer. The Association would be most strongly opposed to any proposal to introduce, in place of judicial hanging, a method of execution which would require the services of a medical practitioner, either in carrying out the actual process of killing or in instructing others in the technique of the process".

744. It will be convenient to consider this last reason before the other two. We of course respect the attitude of the British Medical Association, but we think they may have magnified its probable consequences. A later medical witness thought that the profession would treat the question as one of individual conscience, and not all doctors would feel debarred from giving instruction for such a purpose. Moreover, it is not only within the profession that the necessary skill is to be found. There are many outside it who are fully competent either to give injections themselves or to train others to do it. Laboratory technicians engaged on research work that requires them to give intravenous injections to small animals become extremely skillful. No one can say beforehand to what extent it would be possible either to get volunteer executioners among persons already skilled, or to arrange for training unskilled persons to act as executioners and for giving them the constant practice in venepuncture necessary to maintain their skill. That there are plenty of potential difficulties is obvious. How many and how serious they would prove to be must remain conjectural until tested by experience; we assume that, if this method of execution were to be introduced, the date when the change took effect would have to be left to be determined by administrative action, after time had been allowed for making the necessary arrangements. Our evidence does not justify a conclusion that the difficulty of getting executioners, if it were the only obstacle in the way of a desirable reform, would prove insuperable.

[2] Low, Q. 8955.

[3] p. 318 (27).

745. But it is by no means the only obstacle. The question raised by the first and second reasons admits of no easy answer. What is to be done if an intravenous injection is not feasible, or feasible only after delay and perhaps a struggle? A possible answer is that hanging should remain the standard method of execution, but that the condemned man, except in the rare cases where he is of unsuitable physique, should be offered intravenous injection as an alternative. If he chose it, he might presumably be relied on not to resist it. This is what our anaesthetist witnesses thought ought to be done.

> "It should be offered as an alternative, pleasanter, method of execution, and should be used only when it has been willingly accepted."[4]

746. This solution would have incidental advantages. It would afford a gradual and experimental way of introducing an untried system, and it might facilitate the provision of executioners, since what would be needed of them could be represented rather as an act of mercy than as an execution. But the contrary arguments are formidable. The practical disadvantages are easy to picture—the inequity of offering a choice to some that might have to be denied to others because of their physical characteristics, the vacillation that might be evoked in a prisoner by having to make so crucial a decision, a vacillation tormenting to himself and embarrassing to the authori-

[4] p. 678A (7).

ties, and the need to have the hangman waiting in the background in case his services should be required after all, gradually perhaps losing his skill from disuse. Even more important, we think, is the argument that it is the duty of any state that inflicts capital punishment to decide for itself what is the proper method of carrying it out, to use that method invariably, and to take all possible means to ensure that the act is performed with dignity, solemnity, speed and certainty.

747. The argument thus points towards the conclusion that, if lethal injection were to be instituted as the method of judicial execution, intramuscular injection would have to be used when intravenous was not feasible. Intramuscular injection is always feasible. As we have said, it needs little skill, and death can be ensured as certainly as by venepuncture. Complete immobility is not necessary: an injection could be given in the thigh through a cut in the trousers, or the needle could even be put through the clothes. But the intramuscular method has the disadvantages that the injection of the fluid might be painful and that it works comparatively slowly. How much pain might be caused by a lethal dose, and how long it would take to be effective, no one, for obvious reasons, can say with certainty. But it seems clear that the time would be a matter of minutes rather than seconds; at best, execution by intramuscular injection would be an appreciably slower process than by venepuncture. We are thus brought back to the question, touched on in paragraph 736, whether a condemned man might be rendered unconscious before being executed. We discussed this with medical witnesses. A sedative to induce unconsciousness could be given either by intramuscular injection or by the mouth. The degree of pain that may be caused by an intramuscular injection depends mainly on the size of the dose: a sedative dose should not be as painful as a lethal one. But the injection of even a sedative dose might be accompanied by some pain; and if, to minimise this, the dose were reduced, it would take longer to act.

For this reason a sedative given by the mouth would be preferable. This alternative, however—apart from the obvious difficulty that the draught might be refused—is said to be open to certain objections of principle. If the time for giving the dose were the morning of the execution, its administration would become in effect part of the process of execution, in which no doctor would think it right to participate. If the time were the night before, this too would require unprofessional conduct from any doctor asked to give it. No doctor (so we were told) could ever properly give to anyone a larger dose than the maximum ordinarily used for therapeutic purposes. Such a dose would not be enough to make sure that the condemned man would be unconscious in the morning. Individual reaction to drugs varies greatly, and to ensure unconsciousness in the morning it would be necessary to give a dose so strong that it might even prove fatal to anyone specially susceptible to the drug. Here arises another objection of principle. It was represented to us that, if death were thus caused unintentionally, by a method other than that prescribed by law, the Home Secretary might find himself in a most awkward predicament. This last objection, however, is legalistic, and could presumably be removed by an alteration of the law. Nor does there seem to be any great difficulty in meeting the objections based on the doctor's professional code, if arrangements could be made—as they presumably could—for the dose to be a pharmaceutically standardised one which could be prepared by a layman. There would still remain the difficulty that the condemned man might refuse the dose, and have to be made unconscious by intramuscular injection, perhaps not wholly painlessly.

748. Before ending our exposition of the facts and arguments bearing on lethal injection, we ought to mention an argument of a general kind put to us against the adoption of any such method of execution. It is akin to the argument in the passage we have quoted from the evidence of the prison chaplains, "If a man is to die, let him

walk to his death cleanly". By general consent one of the prime requisites of any form of capital punishment is that it should admit of being so carried out as to minimise the risk of distressing and unseemly scenes of panic and resistance. Those of our witnesses who have the duty of attending executions gave striking and unanimous testimony to the stoicism with which condemned men—and women—almost always face death on the scaffold. Mr. Pierrepoint told us that in all his long experience he had known only one struggle, and that was at an execution of an alien convicted not of murder but under the Treachery Act.[5] The argument we are now concerned with rests on the belief, supported by this experience, that human nature is so constituted as to make it easier for a condemned man to show courage and composure in his last moments if the final act required of him is a positive one, such as walking to the scaffold, than if it is mere passivity, like awaiting the prick of a needle. We state this argument without comment, to complete the marshalling of our material. As with so many of the arguments on this topic, everyone will be disposed to judge it subjectively, according to his own idiosyncrasy.

Conclusion

749. It is not easy, on a question such as this, to reach conclusions solidly based on factual evidence and reasoned argument. Any assessment of an untried method of execution is bound to be largely conjectural, and subjective bias intrudes irresistibly. Our own collective verdict must be a negative one: we cannot agree to recommend that in present circumstances lethal injection should be substituted for hanging as the method of judicial execution in this country. If we could have been satisfied that executions could be carried out in this way quickly, painlessly and decently in all cases, we should have recommended its adoption unanimously. But we are bound to

[5] Q. 8405-9.

conclude from our expert evidence that there is not at present a reasonable certainty of this. We do, however, recommend, unanimously and emphatically, that the question should be periodically examined, especially in the light of progress made in the science of anaesthetics, with a view to a change of system being proposed to Parliament as soon as it can be shown that there are no longer any grounds for the doubts that now defer us from recommending it.

• • • • •

EXHIBIT 2

Manufacturers

Abbott Laboratories
North Chicago, Illinois 60064

Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park
North Carolina 27709

Eli Lilly and Company
307 E. McCarty Street
Indianapolis, Indiana 46225
P.O. Box 618
Indianapolis, Indiana 46206

Invenex Laboratories
5885 Lakehurst Drive
Orlando, Florida 32809

Squibb & Sons, Inc.
General Offices
P.O. Box 4000
Princeton, New Jersey

Prisons

Warden Al Murphy
Oklahoma State Penitentiary
P.O. Box 97
McAlester, Oklahoma 74501

Acting Warden Felix Rodriguez (through 12/31/80)
Warden Harvey Wimans (as of 1/1/81)
P.O. Box 1059
Santa Fe, New Mexico 87501

Warden Darcol Gardener
Idaho State Correctional Institution
P.O. Box 7309
Boise, Idaho 83707

Warden Billy McMillan
Ellis Unit
Texas Department of Correction
Route 6
Huntsville, Texas 77340

State Department of Corrections

Mr. W. J. Estelle, Jr., Director
Texas Department of Corrections
P.O. Box 99
Huntsville, Texas 77340

Mr. Larry Meachum, Director
Oklahoma Department of Corrections
3400 N. Eastern
P.O. Box 11443
Oklahoma City, Oklahoma 73111

Mr. Paul Shoemaker, Director
Adult Institutions
New Mexico Department of Corrections
and Rehabilitation
113 Washington Avenue
Santa Fe, New Mexico 87501

Mr. C. W. Crowl, Director
Idaho State Department of Correction
P.O. Box 7309
Boise, Idaho 83707

AFFIDAVIT OF DR. WARD CASSCELLS

CITY OF BOSTON)
) ss:
STATE OF MASSACHUSETTS)

I, Dr. Ward Casscells, on oath depose and say that I am co-author of the article "The Ethics of Medical Participation in Capital Punishment By Intravenous Drug Injection" (Attachment 1), herein adopted by reference, published in the January 24, 1980, edition of The New England Journal of Medicine. My curriculum vitae is attached (Attachment 2). The thesis of this article is that a physician's preparation, administration or supervision of a lethal injection would be a perversion of biomedical knowledge and skill for a nonmedical purpose which would violate the ethical principles of the medical profession and the medical practice act of any American jurisdiction. Since the publication of this article, several professional medical and psychiatric associations have formally adopted or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a legally authorized execution of death.

The American Medical Association's ("AMA") governing body, the House of Delegates, adopted the following recommendation of the AMA Judicial Council on July 22, 1980:

> "A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution."

This AMA guideline applies to members of the Oklahoma Medical Association who, as members of that "unified" professional organization, are also all members of the AMA.

The Council of the New Mexico Medical Association endorsed the AMA position on the non-participation of physicians in lethal injections on August 2, 1980.

The Idaho Medical Association's House of Delegates adopted a resolution on July 26, 1980, advising its members not to participate in legal executions by administration of a lethal substance because "it is contrary to medical ethics for a physician to take a human life under any circumstances." The Idaho Medical Association formally stated that "a physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

The Texas Medical Association Board of Councilors on May 11, 1977, declared that a physician, by virtue of the Hippocratic Oath, cannot take a life under any circumstances. The Board at that time unanimously agreed to adopt the following opinion:

> "A physician may be present at a chemical execution for the sole purpose of pronouncing legal death."

This position was reaffirmed by the Board of Councilors in May 1980.

The Board of Trustees of the American Psychiatric Association ("APA") approved the following statement on June 20, 1980:

> "The physician's serving the state as an executioner, either directly or indirectly, is a perversion of medical ethics and of his or her role as healer and comforter.
>
> "APA therefore strongly opposes any participation by psychiatrists in capital punishment, that is, in activities leading directly or indirectly to the death of a condemned person as a legitimate medical procedure."

In addition to these recently adopted resolutions, general ethical principles of the medical profession have long condemned medical participation in lethal injections. The language of the Hippocratic Oath is quite specific:

> "I will use treatment to help the sick according to my ability and judgment, but never with a view to

> injury and wrong-doing. Neither will I administer a poison to anyone when asked to do so nor will I suggest such a course."

The modern version of the Oath, the World Medical Association's Declaration of Geneva, states, "even under threat, I will not use my medical knowledge contrary to the laws of humanity." This provision was adopted in 1948 in direct response to the atrocities committed by medical personnel in Nazi Germany. Several international organizations have also condemned the physician's participation as an instrument of the state in imposing punishment. At the Conference for the Abolition of Torture, held in Paris in 1973, the medical commission declared:

> "Medical and associated personnel shall refuse to allow their professional or research skills to be exploited in any way for the purpose of torture, interrogation, or punishment, nor shall they participate in the training of others for such purpose."

The Guidelines for Medical Doctors Concerning Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment in Relation to Detention and Imprisonment, otherwise known as the Declaration of Tokyo, adopted by the Twenty-Ninth World Medical Assembly of the World Medical Association in October 1975, also contains principles which would prohibit a physician's participation in a lethal injection.

Aside from the ethical principles of the medical profession which condemn a physician's participation in a lethal injection, a physician's preparation, administration or supervision of a lethal injection would not be normal medical practice but rather a perversion of biomedical knowledge and skill for a nonmedical purpose. No physicians are trained to prepare lethal "medications" for human administration; few, if any, physicians would have experience in administering poisons or medication overdoses continuously to the point of death.

It appears that licensing laws and ethical standards for nurses and medical technicians would prevent them from carrying out a lethal injection if physicians did not participate because such personnel do not have the authority to prepare or administer a drug dosage independent of a physician's specific order or valid standing orders. Furthermore, such personnel would be even less experienced than physicians carrying out intentional lethal drug injections since they would be less likely to have worked with laboratory animals. The ethical principles which prohibit physicians from participating in a lethal injection would also make it improper for physicians to train persons to perform lethal injections, assuming physicians even possessed the skills and knowledge to provide the training.

Finally, it is by no means clear that lethal injections is a more humane means of execution than the traditional methods. Electrocution, for example, based on what medical science knows about the brain and the effect of electricity applied to the brain, is presumed to render one unconscious instantly. It is quite possible that electrocutions, although gruesome to watch, are less painful, quicker and more reliable than any drug injection. The same might be said of the gas chamber or even hanging, which the Report of the Royal Committee on Capital Punishment presented to the English Parliament in 1953 supported over lethal injection for a variety of reasons.

/s/ Ward Casscells
WARD CASSCELLS, M.D.

SUBSCRIBED and SWORN TO before me
this 12 day of December, 1980.

/s/ Ronald Aronson
RONALD ARONSON
Notary Public
Commonwealth of Massachusetts
My Commission Expires:

ATTACHMENT 1

THE ETHICS OF MEDICAL PARTICIPATION IN CAPITAL PUNISHMENT BY INTRAVENOUS DRUG INJECTION

FOUR states have now passed legislation that adopts a new method of capital punishment—death by drug injection. The method entails injection of a lethal dose of a drug prepared for that purpose and administered and monitored by medically trained personnel. The growing adoption of these programs raises serious ethical issues for American physicians about their continued and expanded participation in state-ordered execution of human beings for crimes.

THE NEW LAWS

Oklahoma and Texas became the first states to mandate the new system with laws passed almost simultaneously in the spring of 1977. Oklahoma's law provides that the death sentence be carried out by "continuous intravenous administration of a lethal quantity of an ultra-short acting barbiturate in combination with a chemical paralytic agent until death is pronounced by a licensed physician." [1]

Idaho and New Mexico have since enacted similar death-by-injection laws. Florida is very close to enacting such legislation, and other states are considering similar programs. The objectives of the laws are clear enough. It is expected, first of all, that the method will be considered less painful and thus more humane to the condemned prisoner.[2] Secondly, it is hoped that the new method will encourage more juries to vote the death penalty. An Oklahoma newspaper observed, "The most telling point in favor of the drug method is that it might restore the death penalty to actual use." [3] A third objective is constitutional: it is hoped that statutes providing for execution by this method will be less apt to be struck down by the courts as " cruel and unusual punishment." [4] A fourth objective is economic: the method is considerably less expensive than death by electrocution or lethal gas (the construction of a gas chamber for official executions in Oklahoma was estimated to cost over $300,000 [5]).

The total number of condemned persons subject to execution under these laws in these states plus Florida is by no means small. Florida ranks first in the nation with 139 men and one woman on death row. Texas is second with 119. Oklahoma is seventh with 19. Idaho with one is ranked twenty-third. New Mexico has no prisoners under the death sentence.

ROLES OF MEDICAL PERSONNEL

Medical professional participation in these programs can involve a variety of roles, from ordering the substance and preparing it for injection, to injecting the substance or ordering and supervising the injection by other medical personnel, to monitoring the administration and observing the prisoner throughout the continuous injection of the drug, and, lastly, to examining the prisoner and pronouncing his death.

The procedure in Oklahoma, for example, requires that the medical director of the Department of Corrections "shall order a sufficient quantity of the [toxic] substance." [6] It is provided that the drug be sodium thiopental combined with tubocurarine or succincylcholine or potassium chloride. None of the laws requires specifically that a physician personally administer the lethal dosage directly into the prisoner's body. However, none of the laws and none of the policies or procedures adopted in the four states preclude physicians from starting the injections. In Oklahoma it is provided that "a trained medical employee shall insert the catheter and other monitoring equipment." An examining physician is required to inspect the catheter and equipment and to de-

termine "that the fluid will flow into the vein." All the laws require that death be pronounced by a licensed physician in attendance at the execution.

History

There is nothing new about medical participation in state executions. Doctors have been present at and have had roles in official executions for centuries. The guillotine was invented by a dedicated physician and social reformer who opposed the death penalty; the invention was thought to be a more humane method of killing.[7] In this country in 1887 a commission of physicians opposed execution by hanging because of its frequent bungling and resultant prolonged suffering and because it lowered the dignity of the law by its public spectacle. The commission recommended more humane forms of killing, including electrocution, cyanide poisoning, chloroform overdosing, and intravenous injection of morphine. They favored electrocution over the chemical methods.[8] Thomas Edison supported the use of electricity for executions.[9]

Physicians have also been strong and vocal opponents of capital punishment by any method. Among the best known have been Benjamin Rush, B. W. Richardson, Louis J. West, and Karl Menninger. West observed, however, that the voices of physicians were not successful in "inspiring notable action" within the profession. He found this particularly regrettable because of the general respect in which physicians were held in America. West felt that a powerful move would be "a national medical declaration that henceforth it would be considered professionally unethical for a physician to lend his presence to an execution, even as an official examiner to certify the fact and time of death." [10]

Ethics

It is our contention that the ethical principles of the medical profession worldwide should be interpreted to

unconditionally condemn medical participation in this new form of capital punishment.

The Hippocratic Oath itself is the foundation of this position. Its essential purpose was to identify the Greek group of physicians as healers who would never kill or harm their patients. The language is quite specific: "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing. Neither will I administer a poison to anyone when asked to do so nor will I suggest such a course." [11] The modern version of the Oath, the World Medical Association's Declaration of Geneva, states, "even under threat, I will not use my medical knowledge contrary to the laws of humanity." [12] This provision was adopted in 1948 in direct response to the atrocities then so recently committed by medical personnel in Nazi Germany.[13] The war-crimes trials after World War II were then still going on, and the defense of the physicians accused of crimes against humanity was uniformly that they were ordered officially to perform the actions under threat of personal punishment or loss of their positions. The defense was rejected as a violation of the moral imperative to refuse to kill or to harm the prisoners, or to take part in the atrocities in any way.

It is important to recognize that such practices have not been limited to one country or one time. In the Soviet prison camps, according to Solzhenitsyn:

> The prison doctor was the interrogator's and the executioner's right hand man. The beaten prisoner would come to on the floor only to hear the doctor's voice: you can continue, the pulse is normal . . . If the prisoner is beaten to death he signs the death certificate: 'cirrhosis of the liver' or 'coronary occlusion.' He gets an urgent call to a dying prisoner and takes his time. And whoever behaves differently is not kept on in the prison.[14]

Amnesty international has documented the participation of physicians in recent years in the torture of pris-

oners in Chile, Iran, Paraguay, Portugal, and Argentina.[15,16] Clearly these are extremes. However, American physicians have aided long interrogations of accused persons by conducting medical examinations before and after such questioning to certify that the person is physically fit to be questioned, or have certified that the person is not under the influence of drugs taken previously. Physicians have pumped out the stomachs of arrested persons to recover drugs or other contraband. They have operated to remove bullets from prisoners' bodies against their wills in order to have the bullets examined in connection with a crime. Courts have later held some of these practices to be improper searches and in violation of the Constitution."

International Ethical Principles

Various international bodies have considered these issues and have condemned medical professional participation, whether personally or in a supervisory capacity, in such practices as prolonged questioning, forced feeding, physical or mental torture, and ordered punishment. At the Conference for the Abolition of Torture, held in Paris in 1973, the medical commission declared: "Medical and associated personnel shall refuse to allow their professional or research skills to be exploited in any way for the purpose of torture, interrogation, or punishment, nor shall they participate in the training of others for such purpose." [18]

The most important of the international pronouncements came two years later, in October 1975, when the Twenty-ninth World Medical Assembly of the World Medical Association adopted the "Guidelines for Medical Doctors Concerning Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment in Relation to Detention and Imprisonment," otherwise known as the Declaration of Tokyo.[19] The preamble includes the statement: "The utmost respect for human life is to be maintained even under threat, and no use made of any medical knowledge contrary to the laws of humanity."

The Declaration contains six Principles, three of which are particularly relevant to our discussion. In Principle 1 it is stated that the doctor shall not countenance, condone, or participate in any practice of torture or inhumane or degrading procedure, no matter what the offense the person is charged with or convicted of having committed; murder or other capital offenses are not excluded from this provision. In Principle 2 the doctor is prohibited from providing "the premises, instruments, substances, or knowledge to facilitate the practice of torture or other forms of cruel, inhumane or degrading treatment or to diminish the ability of the victim to resist such treatment." The medical professional person who orders or prepares a chemical substance to kill a prisoner under sentence of death would be in direct violation of this principle. It would also be a violation to order or prepare "a short-acting barbiturate" designed to anesthetize the victim so as to cause coma and thus eliminate resistance or pain reaction to the accompanying administration of a lethal, painful poison. The last provides Principle 3, relates to the presence by physicians at the administration of torture or inhumane or degrading treatment—it is strictly forbidden. This prohibition would seem to cover active medical participation by monitoring of the administration of a lethal drug as well as mere passive observation of torture or inhumane punishment.

The Declaration of Tokyo does not deal directly with capital punishment. Torture is defined in the Declaration, but no listing is given of all forms of inhumane treatment or punishment that are condemned as violations of the laws of humanity.

Capital Punishment

Many of the major nations of the world have eliminated capital punishment for crime, and others have

severely limited its application. The United States Supreme Court in 1972 ruled that capital punishment was "cruel and unusual punishment" under the Constitution and laid down strict rules that would allow states to install such punishment only under limited conditions.[20] Justice Brennan, in his concurring opinion, wrote:

> The primary principle is that a punishment must not be so severe as to be degrading to the dignity of human beings . . . More than the presence of pain, however, is comprehended in the judgment that the extreme severity of a punishment makes it degrading to the dignity of human beings . . . When we realize why [former methods] have been condemned, however, we realize that the pain involved is not the only reason. The true significance of these punishments is that they treat members of the human race as non-humans, as objects to be toyed with and discarded.

The various statutes adopted since this decision have been attempts to stay within the guidelines laid down by the Court. It has been argued that the death-by-injection statutes would be within the guidelines.[21] The mere fact that the method is new does not strike it down as unconstitutional. The phrase "cruel and unusual" is read cumulatively so that the new method must be unusually cruel and inhumane to violate the standard.[22]

Ethical, Legal and Clinical Concerns Regarding the New Procedure

Physician or other medical participation in carrying out a death sentence by intentional, careful, skillful injection of a medically prepared substance into the veins of the prisoner seems to us to constitute a grievous expansion of medical condonation of and participation in capital punishment. It is a more obvious application of biomedical knowledge and skills than any other method

of execution yet adopted by any other nation in modern history. The preparation of the substance, either of a toxic nature alone or in combination with hypnotics or analgesics, would require special knowledge and skills in pharmacology and toxicology. Yet to call such planned killing a medically acquired skill would, we submit, be erroneous. No physicians are trained to prepare lethal "medications" for human administration; few, if any, physicians would have experience in administering poisons or medication overdoses continuously to the point of death. Thus, requiring a physician to prepare and to administer or to supervise such a procedure would not be normal medical practice; it would be a perversion of biomedical knowledge and skill for a nonmedical purpose. It would, in our judgment, violate the medical practice act of any American jurisdiction.

Supervision by a physician of the actual administration of the lethal dosage by other "employment medical personnel" should be equally condemned ethically and legally. The physician should not escape moral responsibility by ordering a subordinate to do what he or she may not properly do directly. As a practical matter, the physician would need to be ready to intervene should the nurse or technician have difficulty with the catheterization. The physician might be required to do a venous cutdown or to perform other medical emergency procedures.

Could other medically trained personnel take over and perform all actions to cause the death by injection? An Associated Press dispatch (*New York Times*, Dec. 9) indicates that the Oklahoma program will use three "volunteer medical technicians" to actually administer the injection. They will stand behind a barrier, and each will inject a substance into a tube running through the barrier and into the prisoner's body. One of the substances will be lethal; none of the volunteers will know which substance was the lethal dose. A Corrections De-

partment official is quoted as saying it is "sort of a firing squad approach."

In analogous situations, legal reasoning in court cases has been to the effect that under these circumstances, rather than avoiding legal and moral responsibility, all three actors would be fully responsible for the death, since each understands and intends to kill if the lethal substance happens to be theirs at the time.

Nothing is said in the news item about who prepares the injection or inserts the instrument into the pisoner's body, or selects which of the three tubes will carry the properly prepared lethal dose. Also, nothing is said about who selects the "volunteers," or whether they are correctional employees.

The licensing laws and ethical standards for nurses and medical technicians would sanction no such independent action. Such personnel are authorized to perform medical interventions with patients only under a physician's specific order or valid standing orders. Furthermore, such personnel would be even less experienced in carrying out intentional lethal-drug administrations than physicians since they would be less likely to have worked with laboratory animals. The ethical principles cited earlier would make it improper also for physicians to train persons to perform inhumane treatment or punishment, even if the physicians possessed the skills and knowledge to provide the training.

On the basis of the positions taken above, we believe it would also be ethically improper for physicians to monitor the condemned prisoner's condition during the drug administration and to carry on this action to pronounce his death when heartbeat and respirations were found to be absent. To perform such a continuous role would be so intimately a part of the whole action of killing as to deny any consideration as a separate medical service. The international principles cited earlier make it improper for a physician to be present during the administration of torture or cruel or inhumane punishment. The

medical presence gives the impression of moral sanction by the healing professions. To be both present and performing a monitoring role is worse. It is similar to the physician who examines the prisoner intermittently during torture or prolonged interrogation and pronounces him physically fit to continue his ordeal. The "continuous intravenous injection" ends only when the monitoring physician pronounces the condemned prisoner dead. The physician then becomes the instrument, the order, to stop the lethal action itself. There is no other way to describe this physician's role but as that of an active participant, a key human participant, in the execution.

Other Views

There may be medical colleagues who genuinely disagree with some or all of the positions taken above. Some will support capital punishment and will sanction various methods of quick, relatively painless execution. Some will support medical participation in executions in the interest of administering clinical services to the prisoner, or will support witnessing the execution to assure against unnecessarily harsh handling of the prisoner. To be sure, medicine has for centuries realized that one of its important functions is to comfort and relieve, when unable to cure. Should the dying prisoner be deprived of this service because of the personal qualms or political fears of the doctor? Does the condemned have no "right to health care"? Surely this is begging the issue, as the person soon to be killed by the state is hardly analogous to the dying patient, yet some physicians may well take this view, as was the case in Oklahoma, where some physicians helped initiate the bill.

Some physicians may see only the legislature, or the judge, or the prison official as the instrument or instruments of the death and will excuse employed physicians and technicians as only doing their jobs. Some may see the physicians as performing not a medical service but

a civic duty for social good and the protection of the community. For example, physicians may certainly vote and sit on juries; in these instances however, they are not using their skills to take a life.

Conclusion

The medical profession should examine seriously the issues presented by this new method of capital punishment. We believe that it presents the most serious and intimate challenge in modern American history to active medical participation in state-ordered killing of human beings. Unlike any other methods, this procedure requires the direct application of biomedical knowledge and skills in a corruption and exploitation of the healing profession's role in society. We are also disturbed that this method, viewed as less cruel than other methods of capital punishment, should, by its availability, encourage the more extensive application of the death penalty and its recommendation by lay juries in the criminal courts. The line should be drawn here. The medical profession in the United States should formally condemn all forms of medical participation in this method of capital punishment.

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CURRICULUM VITAE

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Education:

1974	B.S. Yale University, New Haven, Connecticut (Biology, Cum Laude)
1979	M.D. Harvard Medical School, Boston, Massachusetts (Magna Cum Laude)
1979-90	Intern in Medicine, Beth Israel Hospital, Boston, Massachusetts
1980	Resident in Medicine, Beth Israel Hospital, Boston, Massachusetts
1980	Resident in Medicine, Harvard Community Health Plan, Boston, Massachusetts

Prizes:

1979 Leon Resnick Prize for Research

Memberships:

American Heart Association

Aesculapion Society, Harvard Medical School

Harvard Medical School Admissions Committee (1975-1979)

Boards:

National Board of Medical Examiners, Parts I, II, III

Publications:

1. Casscells W, Schoeneberger A, Graboys TB et al: Meralgia Paresthetica Due to Unusual Compression. N Engl J Med. 1978; 29S:285.
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In Press

17. Casscells W: Prognosis of Myocardial Infarction Versus Unstable Angina, N Engl J. Med.

Submitted for Publication

18. Evans DA, Casscells W, Hennekens CH: Retirement and Coronary Disease.
19. Di Silva RA, Henneken CH, Lown B, Casscells W: Lidocaine prophylaxis in acute myocardial infarcation: an evaluation of study design.
20. Casscells W, Goroll AH: Use of the Laboratory for Screening for Disease.
21. Casscells W, Verrier RL, Lown B: Influence of Alpha Adrenergic Blockade on the initiation and maintenance of ventricular fibrillation.

22. Casscells W, Verrier RL, Lown B: Synergistic antifibrillatory effects of Phentolomine and Propranolol in the dog and cat.

23. Casscells W, Verrier RL, Lown B: Mechanism of the antifibrillatory action of Phentolamine.

Current as of 11/80

AFFIDAVIT OF DR. RICHARD S. HODES

STATE OF FLORIDA)
) ss:
CITY OF TAMPA)

I, Dr. Richard S. Hodes, on oath depose and say, that I am a certified Diplomat of the American Board of Anesthesiology and a Fellow of the American College of Anesthesiology; a member of the American Society of Anesthesiologists, the Florida Society of Anesthesiologists and the Academy of Anesthesiology; former president of the Florida Medical Association; former president of the Florida Society of Anesthesiologists; former chairman of the Section on Clinical Care of the American Society of Anesthesiologists; former head of the Section on Anesthesiology at Tampa General Hospital where I founded and directed an approved residency program in anesthesiology; former Clinical Assistant Professor of Anesthesiology at the University of Florida, College of Medicine. I am currently Majority Leader of the Florida House of Representatives where I represent Florida's 68th District, Clinical Professor of Surgery at the University of South Florida, College of Medicine, and a practicing anesthesiologist. My curriculum vitae is attached (Attachment 1).

I am not aware of any published scientific data or information which in any respect address the use of sodium thiopental, tubocurarine, potassium chloride, succinylcholine, or any other drugs as a means of execution or which establish their effectiveness for a quick, painless execution. Nor am I aware of any adequate and well-controlled investigation establishing their effectiveness as drugs for a lethal injection.

The intravenous injection of a lethal dosage of drugs would require professional skill in the actual administration of the drugs as well as in the determination of

the necessary dosage. Execution by intravenous injection would require the placement of a needle or cannula into a vein prior to or immediately before the time of execution. Generally, such placement is more difficult in blacks, obese individuals and individuals with a long history of drug addiction. It would appear, as is the case in current clinical practice, that a standardized protocol cannot be constructed to insure uniform and equal treatment of all individuals. For the cannula to be maintained in position after placement in a resisting individual, constant restraint would be required. Similarly, a needle injection into a vein at the time the drug is injected would be considerably more difficult and unreliable in a resisting individual.

Whether a needle or a cannula is used, there is a risk of extravasation of drugs into the surrounding tissues causing considerable pain and discomfort. As a result of such an occurrence, the drug would not produce its intended result.

A major difficulty of injection as a means of execution is the fact that individual responses to drugs such as thiopental are quite varied. An individual with a long history of exposure to drugs or alcohol might not even lose consciousness with as much as one-half gram. This dose requires a large 20cc syringe since a greater than two and one-half percent concentration produces vein irritation and pain due to the highly alkaline nature of the substance. It is therefore reasonable to state that there can be no positive assurance that individuals would be rendered unconscious in all cases before the paralytic drug is injected. In almost all instances there would be an awareness of the onset of loss of consciousness. In the conscious individual, curare will produce a sense of shortness of breath and suffocation. An awareness is present since the effect is gradual with an onset over a two to three minute period. The effect of succinylcholine in the conscious individual is at first a sensation of multiple elec-

tric shocks over the entire body with erratic muscle twitching followed by acute paralysis and suffocation.

Even in the most well-controlled clinical situations, miscalculations as to the depth of unconsciousness produced by thiopental have been made. It would be reasonable to anticipate that in the excited individual facing execution the likelihood of this error is substantially greater. There is insufficient data to allow the use of sodium thiopental, succinylcholine chloride, tubocurarine, potassium chloride and the other drugs cited as possible alternatives, as a so-called quick and painless means of execution.

/s/ Richard S. Hodes
RICHARD S. HODES, M.D.

SUBSCRIBED AND SWORN TO before me
this 11th day of December, 1980.

/s/ Yvonne E. Mathison
Notary Public

My Commission Expires: July 19, 1983

CURRICULUM VITAE

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Born: April 24, 1924, New York, New York

Education:

Miami Beach High School, 1940

Tulane University, B.S., 1944

Tulane University School of Medicine, M.D., 1946

Internship:

U.S. Marine Hospital, Staten Island, N.Y., 1946-1947

Fellowship:

Anesthesiology, Univ. of Minnesota, 1949-1951

Military:

Army of United States, 1947-1949, 1st Lieutenant to Captain

Professional:

Private Practice—Anesthesiology, Tampa, Florida, 1951 to present

Professional Associations and Activities

Academic Positions:

Head, Section on Anesthesiology, Tampa General Hospital, 1958-1964. Founded and directed approved residency program in Anesthesiology

Clinical Associate—Anesthesiology, 1961-1967

Clinical Assistant Professor—Anesthesiology, 1967-1973, University of Florida, College of Medicine

Clinical Professor of Surgery, University of South Florida, College of Medicine, 1973 to present

Member:

American Medical Association

Florida Medical Association

Hillsborough County Medical Association

American Society of Anesthesiologists

Florida Society of Anesthesiologists

Academy of Anesthesiology

Certified:

American Board of Anesthesiology

American College of Anesthesiology

Offices:

President, Florida Society of Anesthesiologists, 1960

Chairman, Section on Clinical Care, American Society of Anesthesiologists

Treasurer, Florida Medical Association, 1975-78

Treasurer, Florida Physicians' Insurance Reciprocal, 1975 to date

President, Hillsborough County Medical Association, 1977

President, Florida Medical Association, 1979-80

Medical Director, Professional Foundation for Health Care, Inc., 1980 to date

Public Affairs:

Elected to Florida House of Representatives, 1966 to present, District 68

Chairman of the Committee on Health & Rehabilitation Services, 1968-74

Chairman of the Education Committee, 1974-76

Chairman of the Legislative Staff Intern Program, 1974 to date

Subcommittee Chairman, Appropriations Committee—Educational Appropriations, 1978-80

Member, Rules Committee, Finance and Tax, Retirement, Personnel and Collective Bargaining, 1978-80

Elected by the House as Speaker Pro Tempore, 1978-80

Appointed by the House as Majority Leader, 1981-83

Participant in the 1974 Washington Economic Summit Conference

National Organizations

President of the National Conference of State Legislatures, 1980.

Chairman of the State Federal Assembly of the National Conference of State Legislatures, 1977.

Chairman of the Human Services Resources Task Force of the Intergovernmental Relations Committee of the National Legislative Conference, 1974-76.

Chairman of the National Resources Task Force of the National Legislative Conference, 1972-74.

Member of the Task Force for the National Conference on State Small Business Programs, 1980 to date.

Serves on the Intergovernmental Program Advisory Subcommittee of the National Science Foundation, 1980 to date.

Health and Social Service Areas

Testified before various congressional committees on health and social services over the past 10 years. Represented the National Governors Conference giving testimony on social services revenue sharing before the Senate Finance Committee in 1974.

Member of the Advisory Panel on National Health Insurance to the Subcommittee on Health of the Committee on Ways and Means of the United States House of Representatives, 1976 to date.

President of the Board of Directors of the Human Services Institute for Children and Families, Arlington, Virginia, 1973-75.

Education and Medical Education

Serves on the Advisory Committee for the Southern Regional Education Board, 1976 to date.

Commissioner of the Education Commission of the States, 1975-76.

Member of the Dean's Advisory Committee, University of South Florida College of Medicine, 1975 to date.

Member of the Board of Fellows of the University of Tampa, 1976 to date.

Others

Member of the Board of Directors, Florida West Coast Public Broadcasting, Inc., 1978 to present.

Host of a weekly educational TV talkshow, "It's Your Government", WEDU, Tampa, 1975 to present.

Member of the Board of Directors, Canterbury Towers, 1979 to present.

Member of the Board of Directors of the Hillsborough County Association for Retarded Citizens, 1968-72.

As a member of the Governmental Operations Committee was a major architect of the State Department of Health & Rehabilitative Services in 1969 during a constitutionally mandated executive reorganization. Served in the House of Representatives in 1968 when Legislature by resolution proposed a new constitution adopted by the people of Florida. Executive reorganization accomplished using Booz, Allen as management consultants.

Awards:

Recipient of the FEA/United of Florida Award for outstanding service to education, 1976, 1979, 1980.

Award for recognition of health needs of the infants and children of Florida, the Florida Pediatric Society, Florida Chapter, American Academy of Pediatrics, 1977-78.

State Humanitarian award for outstanding community service from the National Conference of Christians and Jews, 1979.

Legislative Service Award, Florida Association of Community Colleges, 1978, 1979.

A. H. Robbins Community Service Award for outstanding community service by a physician, 1975.

Nominated for the St. Petersburg Times Award in 1971, 1972, 1975, 1976 as "Most Valuable Member of the House".

Florida Jaycees State Good Government Award, 1970.

Distinguished Service Award, Florida Voluntary Health Association, 1970.

Distinguished Citizen Award, Florida Association for Gifted Children, 1969.

Award for distinguished service in the passage of historical 1968 Exceptional Child Legislation by the Florida Association for Retarded Children, 1968.

Publications:

Auxiliary Myocardial Vascularization by Prosthetic Graft Implantation, S. Smith, M. Beasly, R. Hodes & Others, Surg., Gyn., and Obs., 1957, 104: 263-268.

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) ss:
STATE OF MASSACHUSETTS)

I, Dr. Leroy David Vandam, Ph.B. (Brown University, 1934), M.D. (New York University, 1938), M.A. Hon. (Harvard University, 1968), on oath depose and say that I have extensive training in pathology, surgery, surgical research, anesthetic and pharmacological research, writing, teaching and academic work. My curriculum vitae and bibliography are attached. I am currently Professor of Anesthesia, Emeritus, at Harvard Medical School, Anesthesiologist to the Peter Bent Brigham Hospital in Boston and Director of Anesthesiology at the Hospital at Parker Hill in Boston, a hospital run by the Harvard Community Health Plan.

I am not aware of any published scientific data or information which in any respect address the use of sodium thiopental, tubucurarine, potassium chloride, succinylcholine chloride or any other drugs as a means of execution or which establish their effectiveness as drugs for a quick, painless execution. Nor am I aware of any adequate and well-controlled investigations establishing their effectiveness as drugs for a lethal injection.

The intravenous injection of drugs, such as the short-acting barbiturate thiopental and the neuromuscular blockers succinylcholine and tubocurarine, requires a considerable amount of professional expertise. Even when such an injection is performed by an expert, serious technical difficulties may arise causing the recipient physical and mental pain.

If a person is nervous or fearful, the veins become constricted as a result of sympathetic nervous activity, to wit, the release of adrenalin, thereby increasing the difficulty of performing the injection. Veins are difficult to find and enter in people suffering from obesity, people

with heavily pigmented skin, elderly people with fragile veins, drug addicts whose veins may be thrombosed as a result of prior drug injections and people with a history of diabetes, uremia and some other conditions.

Insertion of a needle into a vein is always painful, even if a local anesthetic is first used. Repeated attempts at finding a vein cause pain and result in the escape of blood into the tissues, with swelling and occlusion of other veins.

In people with flat veins, it is impossible to prevent the needle which has pierced one wall from going through the opposite wall as well. If one of the drugs to be used for lethal injection were accidentally injected into an artery, a not unlikely occurrence, the recipient would experience excruciating pain, the artery would constrict and the surrounding tissues would die, probably with extensive gangrene.

Even if a needle seems to be within a vein, the drug might nevertheless escape into the surrounding tissue upon injection causing pain and swelling. Furthermore, as a result of the drug escaping into the surrounding tissue, the drug would not produce its intended result.

Thiopental is a highly alkaline solution of pH 11.5, which causes local thrombosis of the vein in some people. If it enters tissue, painful neuritis occurs if a nerve is adjacent, and tissue death may also occur. The same observations apply to potassium chloride and acidic solutions such as succinylcholine and tubocurarine.

The determination of the proper dosage of drugs for a lethal injection would also be a difficult task. When used as anesthesia, thiopental and curare are given intermittently in measured amounts until the desired effect is achieved. Even in the controlled setting of the hospital, however, it is not too unusual to have a patient recall operative events when presumably asleep and to experience pain. Dosage for a lethal effect would be determined by age, body mass, physical condition, and current and prior use of other drugs. Further, some people have

inborn genetic responses to drugs which also influence dosage. If thiopental and tubocurarine were given in sequence, one might not be effective before the other. For example, if not enough thiopental were given and it were followed by curare, the prisoner could be awake and he would die in physical and mental agony. This might also occur if the thiopental escaped into the surrounding tissue upon injection or were accidentally injected into an artery.

There is insufficient data to allow the use of sodium thiopental, succinylcholine chloride, tubocurarine, potassium chloride and the other drugs cited as possible alternatives, as a so-called quick and painless means of execution.

/s/ Leroy D. Vandam MD
LEROY DAVID VANDAM, M.D.

SUBSCRIBED and SWORN TO before me
this 12th day of December, 1980.

/s/ Eleanor Tuniss
Notary Public

My Commission Expires: March 12, 1987

CURRICULUM VITAE

LEROY D. VANDAM, M.D.

BORN:	January 19, 1914, New York, New York
1934	Ph. B. (Magna cum Laude) Brown University
1938	M. D. New York University College of Medicine
1967	M. A. (Honorary), Harvard Medical School
1938-39	House Officer, Pathology, Beth Israel Hospital, Boston
1939-41	House Officer, Surgery, Beth Israel Hospital, Boston
1941-42	Research Resident, Surgery, Beth Israel Hospital, Boston
1942-43	Chief Resident, Surgery, Beth Israel Hospital, Boston
1942-43	Teaching Fellow in Surgery, Tufts Medical College
1943	First Ltd., M. C., AUS, 4th Aux., Surgical Group
1943-45	Absence due to illness (September 1943-September 1945)
1945-47	Fellow in Surgery, Johns Hopkins University
1947-49	Resident in Anesthesiology, Hospital of the University of Pennsylvania
1949-50	Instructor in Surgery (Anes), University of Pennsylvania School of Medicine
1949-51	Associate in Surgery (Anes), University of Pennsylvania School of Medicine and Graduate School
1949-54	Physician Anesthetist, Hospital of the University of Pennsylvania
1950-54	Assistant Professor of Anesthesiology, University of Pennsylvania, Graduate School of Medicine
1951-54	Assistant Professor of Anesthesiology in Surgery, University of Pennsylvania

1953	Instructor in Anaesthesia—World Health Organization, Copenhagen
1954-57	Associate Clinical Professor of Anaesthesia, Harvard Medical School, Boston
1954-70	Surgeon, Peter Bent Brigham Hospital, Boston, Massachusetts
1954-70	Director of Anesthesia, Peter Bent Brigham Hospital, Boston
1956-74	Lecturer in Anesthesia, Chelsea Naval Hospital, Chelsea
1956-75	Chairman, Advisory Panel on Anesthesiology to the U. S. Pharmacopeia
1956-62	Associate Editor—Survey of Anesthesiology (Williams and Wilkins Co.)
1957-67	Clinical Professor of Anaesthesia, Harvard Medical School Boston
1958-	Editorial Board—Clinical Pharmacology and Therapeutics (C. V. Mosby Co.)
1960-	Editorial Board—G P
1952-54	Consultant in Anesthesia to:
	Valley Forge Army Hospital, Phoenixville, Pennsylvania
	Veterans Administration Hospital, Philadelphia, Pennsylvania
1954-	West Roxbury Veterans Administration Hospital, West Roxbury, Massachusetts
	Rutland Veterans Administration Hospital, Rutland Heights, Massachusetts
	Children's Hospital Medical Center, Boston, Massachusetts
	Boston Hospital for Women, Boston, Massachusetts
	Burbank Hospital, Fitchburg, Massachusetts

	Nantucket Cottage Hospital, Nantucket, Massachusetts
	Winchester Hospital, Winchester, Massachusetts
	Robert B. Brigham Hospital, Boston, Massachusetts
	Massachusetts Mental Health Center, Boston, Massachusetts
	Cambridge City Hospital, Cambridge, Massachusetts
1970	Beth Israel Hospital, Boston, Massachusetts
1934	Phi Beta Kappa
1934	Society of Sigma Xi
1949	American Society of Anesthesiologists
1950	American Medical Association
1952	John Morgan Society—Pennsylvania
1952	Diplomate, American Board of Anesthesiology
1952	Fellow, American College of Anesthesiology
1954	New York Academy of Sciences
1954	Association of University Anesthetists
1954	Massachusetts Society of Anesthesiologists
1954	Massachusetts Medical Society
1954	New England Society of Anesthesiologists
1960	Aesculapian Club—Harvard Medical School
1960	Alpha Omega Alpha
1962	Academy of Anesthesiology
1962	International Anesthesia Research Society
1962	Fellow American College of Cardiology
1963-64	President, Massachusetts Society of Anesthesiologists
1963	Halsted Surgical Society
1963-65	President, Association of University Anesthetists

1965	Horace Wells Award
1966	Honarary Member, Horace Wells Club
1974	American Arbitration Association
1975	International Medical Society of Paraplegia
1960	Visiting Professor, University of Iowa School of Medicine
1961-70	Editorial Board, Anesthesiology (J. B. Lippincott Co.)
1961	Visiting Professor, University of California School of Medicine, San Francisco
1961	Visiting Professor, College of Physicians and Surgeons, Columbia University
1961-70	National Research Council—Subcommittee on Anesthesia
1962-70	Editor-in-Chief, Anesthesiology (J. B. Lippincott Co.)
1963	Committee on National Halothane Study, National Research Council
1963-65	Training Grant Committee on Surgery, Radiology and Anesthesiology, National Institutes of Health
1964	Dr. Harry Shields Lecturer, Toronto, Canada
1965-66	Pharmacology and Toxocology Training Grant Committee, National Institutes of Health
1965	Visiting Professor, Albert Einstein College of Medicine
1965-70	Chairman, Committee on Anesthesia, National Research Council
1965-	Standing Committee on the Library, Harvard Medical School
1966	Visiting Professor, University of Florida College of Medicine, Gainesville
1966-70	Anesthesiology Training Grant Committee, National Institutes of Health

1966	Ad Hoc Committee on Cardiopulmonary Resuscitation, National Research Council
1967-76	Chairman, Committee on Human Studies, Peter Bent Brigham Hospital
1967-	Professor of Anaesthesia, Harvard Medical School, Boston
1969-	Committee on Publications, Massachusetts Medical Society
1969-	Secretary, Department of Anaesthesia, Harvard Medical School
1970	Visiting Professor, University of Florida School of Medicine, Miami
1970-75	Committee of Revision of The United State Pharmacopeial Convention, Inc.
1970-	Anesthesiologist-in-Chief, Peter Bent Brigham Hospital, Boston
1971-	Medical Advisory Board of the Medical Letter (Drug and Therapeutic Information, Inc.)
1972	Visiting Professor, Case Western Reserve University, Cleveland
1973	FDA—Consultant to the Advisory Committee on Respiratory and Anesthetic Drugs
1973	Visiting Professor, University of Florida School of Medicine Miami
1973	Committee on Women, Harvard Medical School
1974	Visiting Professor, University of Florida College of Medicine, Gainesville
1974	Visiting Professor, University of Arizona Medical School, Tucson
1974	Wesley Bourne Memorial Lecturer, Montreal, Canada
1974	Committee on Human Studies, Harvard Medical School

1975 Stuart C. Cullen Visiting Professor-University of California, San Francisco

1975 Leonard M. Monheim Memorial Lecturer-University of Pittsburgh, Pittsburgh, Pennsylvania

1975 Crawford W. Long Lecturer, Atlanta, Georgia

1975 Visiting Professor, Albert Einstein College of Medicine, New York

1976- Editorial Board, New England Journal of Medicine

1976 Visiting Professor, University of California, Harbor General Hospital

1976 Visiting Professor, Johns Hopkins Hospital Medical School, Baltimore, Maryland

1976 Becton Dickinson Oscar Schwidetsky Memorial Lecturer, Phoenix, Arizona

1976- Conflict of Interest Committee, Peter Bent Brigham Hospital

1977 Wisconsin Society of Anesthesiologists Lecturer-University of Wisconsin, Madison

1977 Visiting Professor-Hartford Hospital-Hartford, CT

1977 Annual Robbins Lecturer-Vanderbilt University, Nashville,

1977 Distinguished Service Award, American Society of Anesthesiologists

1978 Visiting Professor-The New York Hospital-Cornell Medical Center

1978 Visiting Professor West Virginia University Medical Center, Morgantown

1978 N.B. Anderson Lecturer-Case Western Reserve University, Cleveland, OH

1978 Visting Lecturer—24th Regional Meeting, Japanese Society of Anesthesiology, Osaka, Japan

1978 Massachusetts Governors Task Force on Libraries

1978 Mass. Dept. Public Welfare, Cost Effectiveness Committee on Analgesic Drugs

1978 Hyman Ilman Lecturer, Waltham Hospital

1979 Trustee, Boston Medical Library

1979 Southern Society of Anesthesiologists. Annual Lecturer

1979 Ralph Waters Lecture. Midwestern Anesthesia Conference

1979 Graduation Address. Peter Bent Brigham Hospital Nurses

1979 Bert B. Hershenson Memorial Lecture

1979 E.A. Rovenstein Memorial Lecture

1979 President, Boston Medical Library

1979 Committee on Admissions, Harvard Medical School

1979 Anesthesiologist-in-Chief, Harvard Community Health Plan

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6. Bing, R. J., Vandam, L. D., and Gray, F. D., Jr.: Physiological studies in congenital heart disease. Results of preoperative studies in Tetralogy of Fallot, Bull. Johns Hopkins Hosp. 81:121, 1947.
7. Vandam, L. D., Bing, R. J., and Gray, F. D., Jr.: Physiological studies in congenital heart disease. Measurements of the circulation in five selected cases, Bull. Johns Hopkins Hosp. 81:192, 1947.
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18. Dripps, R. D., and Vandam, L. D.: Long-term follow-up of patients who received 10,098 spinal anesthetics. Failure to discover major neurological sequelae, JAMA 156:1486, 1954.

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20. Vandam, L. D.: Some observations on the function of pulmonary structures, Amer. J. Surg. 89:101, 1955.

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tion during ether anesthesia in man, Circulat. Res. 11:287, 1962.

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68. Vandam, L. D.: Clinical pharmacology of the narcotic analgesics, Clin. Pharmacol. Ther. 3:827, 1962.

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70. Vandam, L. D.: Spinal Anesthesia, *in* Anesthesiology, 2nd Edition, Hale, D. E., Editor, Philadelphia, F. A. Davis Co., 1963.

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72. Vandam, L. D.: Unwholesome humours—Editorial, N.E.J.M. 268:556, 1963.

73. Lefemine, A. A., Vandam, L D., Lunzer, S., Schweizer, H. J., and Harken, D. E.: Circulatory dynamics of cardiopulmonary bypass, Amer. J. Cardiol. 11:301, 1963.

74. Vandam, L. D.: Change without alteration—Editorial, Anesthesiology 24:248, 1963.

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85. Vandam, L. D.: Drugs in the treatment of arterial hypotension and shock, *in* Drugs of Choice, Modell, W., Editor, St. Louis, C. V. Mosby Co., 1964.

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January 12, 1981

The Honorable Patricia Roberts Harris
Secretary, Department of Health and
Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Lethal Injection, Docket No. 80P-0513/CP*

Dear Secretary Harris:

This letter supplements the above-referenced petition pertaining to lethal injection filed on December 19, 1980. By way of this supplement, Jerry Joe Bird and Henry Martinez Porter, inmates at the Ellis Unit of the Texas Department of Corrections, and Alton Franks, Carl Morgan, Charles W. Davis and Robyn Parks, inmates at the Oklahoma State Penitentiary, all of whom are under sentence of death by lethal injection, join in the above-referenced petition and request that you take the action sought by this petition.

Sincerely,

/s/ Stephen M. Kristovich
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Hearing Clerk, FDA

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 81-2265

LARRY LEON CHANEY, ET AL., PLAINTIFFS

v.

RICHARD SCHWEIKER, DEFENDANT

ANSWER

First Defense

The Complaint fails to state a claim on which relief can be granted.

Second Defense

Answering the numbered paragraphs in plaintiffs' Complaint and using the same numbering system, the defendant responds as follows:

1. The first sentence of paragraph 1 is denied as a conclusion of law. The second, third, fourth, fifth and sixth sentences are admitted. The seventh sentence contains plaintiffs' characterization of this action and does not require a response by defendant. To the extent a response is deemed necessary, the seventh sentence is denied.

2.-3. Defendant is without sufficient knowledge to form a belief as to the truth of the allegations in paragraphs 2 and 3.

4. Admitted

5.-6. Paragraphs 5 and 6 are denied as conclusions of law. The Court is respectfully referred to the cited statutory provisions.

7. The first sentence of paragraph 7 contains plaintiffs' characterization of this action form which no response is required. To the extent a response is deemed necessary, the first sentence is denied. The second sentence is denied at a conclusion of law.

8. Paragraph 8 contains plaintiffs' characterization of this action for which no response is required. To the extent a response is deemed necessary, paragraph 8 is denied.

9. The first sentence of paragraph 9 is denied as a conclusion of law. The defendant is without information sufficient to form a belief as to the truth of the allegations contained in the second sentence of paragraph 9.

10. The defendant is without information sufficient to form a belief as to the truth of the allegations contained in the first and third sentences of paragraph 10. The second sentence of the paragraph is denied as a conclusion of law. The Court is respectfully referred to the cited statutory provisions and policy and procedure memorandum.

11. Admitted.

12.-14. The allegations in the first sentence of paragraphs 12, 13 and 14 are denied as conclusions of law. The defendants are without information sufficient to form a belief as to the truth of the allegations in the second sentence in those paragraphs. The Court is respectfully referred to the cited statutory provisions, procedures, and regulations.

15.-16. The allegations of paragraphs 15 and 16 are denied as conclusions of law. The Court is respectfully referred to the cited statutory provisions.

17.-19. The defendant is without sufficient knowledge to form a belief as to the truth of the allegations in paragraphs 17, 18, and 19.

20. The allegations of paragraph 20 are admitted, except insofar as they characterize the defendant's actions to enforce the FD&C Act as "stringent." The nature of the defendant's enforcement of the statute in this area has been, as in other areas, subject to the defendant's discretion and has been no more or less stringent than enforcement in other areas.

21. Admitted.

22. The allegations in paragraph 22 are denied as conclusions of law.

23.-24. Admitted.

25. Defendant is without sufficient knowledge to form a belief as to the truth of the allegations and averments in paragraph 25 except to admit that plaintiffs filed a petition with FDA to which three affidavits were attached from alleged medical and scientific experts.

26. The allegations in paragraph 26 regarding the Secretary's obligation under the FD&C Act are denied as a conclusion of law. The remaining allegations of the paragraph are admitted.

27.-28. Paragraphs 27 and 28 are denied as conclusions of law.

The remaining portions of plaintiffs' Complaint contain the prayer for relief to which no response is required. To the extent that a response is required, the defendant denies the remaining portions of plaintiffs' Complaint. The defendant denies all allegations contained in plaintiffs' Complaint which have not been specifically admitted.

The defendant respectfully requests the Court to dismiss this action and award him his costs.

Respectfully submitted,

CHARLES F. C. HUFF
United States Attorney

ROYCE C. LAMBERTH
Assistant United States
Attorney

/s/ Patricia J. Kenney
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Associate Chief Counsel
for Enforcement

Food and Drug Administration

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 81-2265

LARRY LEON CHANEY, ET AL., PLAINTIFFS

v.

RICHARD SCHWEIKER, Secretary of the Department of Health and Human Services, DEFENDANT

DEFENDANT'S OBJECTIONS TO PLAINTIFFS' FIRST SET OF REQUEST FOR ADMISSIONS

The defendant, Richard Schweiker, submits the following objections to plaintiffs' first set of requests for admissions.

Request for Admission No. 1:

That either Abbott Laboratories, manufacturer of sodium thiopental, Eli Lilly Company, manufacturer of tubocurarine, Squibb and Sons, Inc., and Burroughs-Wellcome Company, manufacturers of succinylcholine chloride, nor Invenex Laboratories, manufacturer of potassium chioride, has filed new drug applications seeking authorization for use of these drugs in the lethal injection execution of human beings.

Objections to Request for Admission No. 1:

Defendant objects to any discovery sought in this case as unnecessary, oppressive and unduly burdensome. The defendant is filing a dispositive motion along with these objections, which if granted will resolve the action. The

basis for that motion is that the complaint raises only two issues, both of which are legal in nature. The first issue raises the scope of authority of the defendant under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq*. The second issue raises the question of whether FDA in denying the plaintiffs' petition considered the relevant factors and made no clear error of law. The Court's review is, of course, limited to the administrative record reflecting the agency's reasons for its decision. Consequently, in that matters outside of the administrative record may not be considered by the reviewing Court, any discovery is by definition unnecessary and unduly burdensome.

The request for admission is also objectionable because whether any person has filed a new drug application is, prior to a decision on that application, considered to be a trade secret, commercial confidential information and is not subject to disclosure. *See* 21 C.F.R. § 314.14(b); 21 U.S.C. § 331(j); 18 U.S.C. § 1905

As stated in its dispositive motion, however, defendant notes that no new drug application has been approved for the use of any drug for the lethal injection in connection with the execution of human beings.

Request for Admission No. 2:

That neither Abbott Laboratories, manufacturer of sodium thiopental, Eli Lilly Company, manufacturer of tubocurarine, Squibb and Sons, Inc., and Burroughs-Wellcome Company, manufacturers of succinylcholine chloride, nor Invenex Laboratories, manufacturer of potassium chloride has submitted to the Food and Drug Administration (hereinafter "FDA") any evidence that these drugs are safe and effective for the lethal injection execution of human beings.

Objection to Request for Administration No. 2:

The objections to Request for Administration No. 1 are incorporated by reference.

Request for Admission No. 3:

That there is not substantial evidence that the intravenous injection of a human being with sodium thiopental, tubocurarine, succinylcholine chloride or potassium chloride will produce quick and painless death.

Objection to Request for Admission No. 3:

The objections to Request for Admission No. 1 are incorporated by reference.

Request for Admission No. 4:

That there is no expert consensus in the scientific community founded upon substantial evidence that the intravenous injection of a human being with sodium thiopental, tubocurarine, succinylcholine chloride or potassium chloride will produce quick and painless death.

Objection to Request for Admission No. 4:

The objection to Request for Admission No. 1 is incorporated by reference.

Request for Admission No. 5:

That the FDA is not aware of any adequate and well-controlled investigations, including clinical investigations by experts qualified by scientific training and experience to evaluate the effectiveness of sodium thiopental, tubocurarine, succinylcholine chloride, or potassium chloride, which establish that there are procedures whereby these drugs can be administered intravenously to produce quick and painless deaths of human beings.

Objection to Request for Admission No. 5:

The objection to Request for Admission No. 1 is incorporated by reference.

Respectfully submitted

/s/ Stanley S. Harris
STANLEY S. HARRIS
United States Attorney

/s/ Royce C. Lamberth
ROYCE C. LAMBERTH
Assistant United States Attorney

/s/ Patricia J. Kenney
PATRICIA J. KENNEY
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/s/ Marcia A. Johnson
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 81-2265

LARRY LEON CHANEY, ET AL., PLAINTIFFS

v.

RICHARD SCHWEIKER, Secretary of the Department of Health and Human Services, DEFENDANT

DEFENDANT'S OBJECTIONS TO PLAINTIFFS' FIRST SET OF INTERROGATORIES

The defendant, Richard Schweiker, submits the following objections to plaintiffs' first set of interrogatories, as follows:

Interrogatory No. 1:

In the letter of Commissioner of Food and Drugs Arthur Hull Hayes, Jr., M.D., to David E. Kendall, dated July 7, 1981, a copy of which is attached hereto as Exhibit A (hereinafter "Commissioner's letter"), state the "relevant statutory provisions" referred to in the second paragraph on page 2.

Objections to Interrogatory No. 1:

Defendant objects to any discovery sought in this case as unnecessary, oppressive and unduly burdensome. The defendant is filing a dispositive motion along with these objections, which if granted will resolve the action. The basis for that motion is that the complaint raises only two issues, both of which are legal in nature. The first

issue raises the scope of authority of the defendant under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* The second issue raises the question of whether FDA in denying the plaintiff's petition considered the relevant factors and made no clear error of law. The Court's review is, of course, limited to the administrative record reflecting the agency's reasons for its decision. Consequently, in that matters outside of the administrative record may not be considered by the reviewing Court, any discovery is by definition unnecessary and unduly burdensome.

Interrogatory No. 2:

In the Commissioner's letter, state what is meant by the phrase "our current policy on the use of approved drugs for unapproved uses" in the second paragraph on page 2, state when this policy was adopted, state what the previous policy was and why the policy was changed, and set forth in detail the complete history of the Food and Drug Administration's ("FDA") policy on the use of approved drugs for unapproved uses and the reasons for any changes in the policy.

Objections to Interrogatory No. 2:

The objections to Interrogatory No. 1 are incorporated by reference.

Interrogatory No. 3:

State what criteria the FDA has established to assess the safety and effectiveness of drugs marketed to kill domestic animals.

Objections to Interrogatory No. 3:

The objections to Interrogatory No. 1 are incorporated by reference.

Interrogatory No. 4:

State whether the FDA has established any criteria to assess the safety and effectiveness of drugs used for the lethal injection execution of human beings.

Objections to Interrogatory No. 4:

The objections to Interrogatory No. 1 are incorporated by reference.

Interrogatory No. 5:

State whether the FDA has established that, under certain specified procedures, there is substantial evidence that the intravenous injection of human beings with sodium thiopental, tubocurarine, succinylcholine chloride, or potassium chloride will produce quick and painless death.

Objections to Interrogatory No. 5:

The objections to Interrogatory No. 1 are incorporated by reference.

Interrogatory No. 6:

State whether the FDA has established that there is an expert consensus that the intravenous injection of human beings with sodium thiopental, tubocurarine, succinylcholine chloride, or potassium chloride will produce quick and painless death.

Objections to Interrogatory No. 6:

The objections to Interrogatory No. 1 are incorporated by reference.

Interrogatory No. 7:

State whether the FDA is aware of any adequate and well-controlled investigations, including clinical investigations by experts qualified by scientific training and experi-

ence to evaluate the effectiveness of sodium thiopental, tubocurarine, succinylcholine chloride, or potassium chloride, which establish that there are procedures whereby these drugs can be administered intravenously to produce quick and painless deaths of human beings, and, if the FDA is aware of such investigations, state the dates, places, investigators, and institutions involved, and identify any published summaries of these investigations.

Objections to Interrogatory No. 7:

The objections to Interrogatory No. 1 are incorporated by reference. Moreover, Interrogatory No. 7 is also objectionable to the extent, if at all, it requests information from agency records as to new drugs which are lawfully exempted from the requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, for investigational purposes. To the extent that there is, if at all, any responsive information in investigational new drug files, the agency could not disclose such information because it is regarded as trade secret, commercial confidential information which cannot be disclosed. 21 C.F.R. § 314.14.

Interrogatory No. 8:

In the Commissioner's letter, state what is meant by the phrase "a serious danger to the public health."

Objections to Interrogatory No. 8:

The objections to Interrogatory No. 1 are incorporated by reference.

Interrogatory No. 9:

State whether evidence of the safety and effectiveness of the use of sodium thiopental, tubocurarine, succinylcholine chloride and potassium chloride as execution agents is "pertinent" (Commissioner's letter, second paragraph, page 4) to the FDA's exercise of its "inherent

discretion (*id.*, 4th paragraph, page 3) to pursue certain enforcement matters.

Objections to Interrogatory No. 9:

The objections to Interrogatory No. 1 are incorporated by reference.

Respectfully submitted,

/s/ Stanley S. Harris
STANLEY S. HARRIS
United States Attorney

/s/ Royce C. Lamberth
ROYCE C. LAMBERTH
Assistant United States Attorney

/s/ Patricia J. Kenney
PATRICIA J. KENNEY
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/s/ Marcia A. Johnson
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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 81-2265

LARRY LEON CHANEY, ET AL., PLAINTIFFS

v.

RICHARD SCHWEIKER, Secretary of the Department of Health and Human Services, DEFENDANTS

DEFENDANT'S STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO GENUINE DISPUTE

In accordance with Local Rule 1-9(h) of this Court, the defendant submits the following statement of material facts as to which there is no genuine dispute:

1. By letter dated December 19, 1980, David E. Kendall and Stephen M. Kristovich, attorneys at the law firm of Williams and Connolly, filed a citizens petition in accordance with 21 C.F.R. § 10.30 which requested the FDA to prevent certain states from using certain drugs as a means of administering the death penalty in accordance with procedures authorized by state.

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, prohibits drugs from being marketed in interstate commerce unless they have been generally recognized by experts as safe and effective for a particular indication, or unless they have been demonstrated to be safe and effective by adequate and well-controlled clinical investigations. Consequently, Messrs. Kendall and Kristovich contend that until and unless the drugs used by a state are demonstrated to be safe and effective for bring-

ing about death and are properly labelled, the state should be precluded from using those drugs for an unauthorized purpose. Plaintiffs also contend that FDA lacks discretion not to take enforcement action. Complaint at 1, and Petition (attached as Exhibit A to the Complaint).

2. By letter dated July 7, 1981, the Commissioner of Food and Drugs, Arthur Hull Hayes, Jr., denied the petition of Messrs. Kendall and Kristovich. Commissioner Hayes explained the agency's reasons for the denial. A copy of the July 7, 1981 letter is attached.

3. On September 16, 1981, this suit was filed by various inmates on death row in states authorizing the administration of the death penalty by lethal injection. The inmates seek review of the agency's action on July 7, 1981 in denying the citizens petition filed by Messrs. Kendall and Kristovich.

Respectfully submitted,

/s/ Stanley S. Harris
STANLEY S. HARRIS
United States Attorney

/s/ Royce C. Lamberth
ROYCE C. LAMBERTH
Assistant United States Attorney

/s/ Patricia J. Kenney
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SUPREME COURT OF THE UNITED STATES

No. 83-1878

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL.

ORDER ALLOWING CERTIORARI

Filed June 18, 1984

The petition herein for a writ of certiorari to the *United States Court of Appeals for the District of Columbia* is granted.

☆ U. S. GOVERNMENT PRINTING OFFICE: 1984 447239 11001

AMICUS CURIAE

BRIEF

Office Supreme Court, U.S.
FILED
AUG 16 1984
ALEXANDER L. STEVAS,
CLERK

No. 83-1878

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

LARRY LEON CHANEY, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF AMICUS CURIAE THE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF REVERSAL

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WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

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QUESTIONS PRESENTED

1. Whether certain chemical substances used by states for lawful execution of condemned capital felons constitute "drugs" within the meaning of the Food, Drug, and Cosmetic Act ("FDCA") in connection with that particular use.

2. Whether interference by federal agents with the implementation of constitutional capital punishment sentences by state officials, under the purported authority of the FDCA's drug regulation requirements, would violate the Tenth Amendment to the U.S. Constitution.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

No. 83-1878

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

LARRY LEON CHANEY, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF AMICUS CURIAE THE WASHINGTON LEGAL FOUNDATION

INTEREST OF AMICUS CURIAE WASHINGTON LEGAL FOUNDATION

The Washington Legal Foundation (WLF or Foundation) is a national nonprofit public interest law center that engages in litigation and the administrative process in matters affecting the public and national interest. WLF has more than 200,000 members and supporters throughout the United States—including the states of Texas and Oklahoma—whose interests the Foundation represents.

WLF devotes a substantial portion of its resources to matters involving criminal justice and related constitutional issues. The Foundation's commitment to the rights, well-being, and vindication of the victims of violent crime is reflected in the establishment of WLF's Crime Victims' Program. This program is designed to advance the rights of crime victims and help reduce the alarming crime rate in America. Among other activities, WLF provides educational materials, legal guidance, and assistance to the victims of violent crime, participates in rulemaking proceedings before agencies such as the United States Parole Commission, and monitors criminal cases in which the courts have been too lenient in sentencing violent criminals or have otherwise exhibited an insensitivity to the rights of victims and the general public.

As part of its Death Penalty Project, WLF has appeared as *amicus curiae* in the following death penalty cases before this Court: *Strickland v. Washington*, No. 82-1554 (U.S. Sup. Ct. 1983); *Barefoot v. Estelle*, 103 S. Ct. 3383 (1983); *Enmund v. Florida*, 102 S. Ct. 3368 (1982); *Zant v. Stephens*, 456 U.S. 410 (1982); and *Eddings v. Oklahoma*, 455 U.S. 104 (1982).

WLF attorneys have also testified before the U.S. Congress on capital punishment issues, see, e.g., *Hearings on H.R. 5679 Regarding A Federal Death Penalty Before the Subcommittee on Criminal Justice of the House Committee on the Judiciary*, 97th Cong., 2d Sess. (1982) (statement of the Washington Legal Foundation), and regularly debate opponents of capital punishment in a variety of public forums.

In this case, the Foundation seeks to advance the interests of its members by seeking reversal of a decision which, if upheld, could severely undermine the states' ability to enforce valid and constitutional criminal penalties. The D.C. Circuit's bizarre application of federal

drug legislation to state capital punishment methods represents a dangerous and disturbing manifestation of judicial excess. Expanding the scope of the Food, Drug, and Cosmetic Act in a manner never remotely contemplated by Congress, the court usurps the legislative function; compelling the FDA to interfere with the states' authority to enforce criminal penalties, the court dictates an unprecedented encroachment on one of the remaining state functions presumed sacrosanct under the Tenth Amendment.

Moreover, the D.C. Circuit's decision would create a bizarre new device for collateral review of lawful death sentences which would unconstitutionally circumvent the well-established contours of judicial review under the Eighth Amendment.

Thus, the decision below strikes indiscriminately at the principles of separation of powers, constitutional federalism, and the integrity of law enforcement itself.

As *amicus curiae*, WLF will contribute to the Court's consideration of this case by addressing certain important issues—i.e., the Court of Appeals' distortion of the definition of a "drug" and the significant Tenth Amendment intrusion—which existing parties may not be disposed to pursue.

STATEMENT OF THE CASE

In the interests of judicial economy, *amicus* adopts by reference the statement of the case set forth at pages 2-6 of the Petition for a Writ of Certiorari filed in this case.

SUMMARY OF ARGUMENT

The D.C. Circuit erred in holding that the Food, Drug, and Cosmetic Act ("FDCA" or "Act") requires the Food and Drug Administration ("FDA") to regulate the states' use of certain chemicals in carrying out lawful executions by lethal injection.

Although the chemicals in question are treated as "approved drugs" in connection with other uses, their distinct use for capital punishment must be separately analyzed to determine whether the Act's coverage extends to that application. When used by states for lawful executions, the injection substances do not constitute "drugs" subject to FDA regulation. That particular use does not fall within the Act's purpose of protecting consumers from the dangers of items which are marketed on the basis of misleading representations as to therapeutic or health benefits.

If this Court were to affirm the decision below, FDA regulation of *all* methods of capital punishment would inevitably follow. The injections at issue would be treated as "drugs" because their intended effect on the functions of the body of man—i.e., to cause death by execution—would be deemed to meet the Act's definitional requirements. Since the intended effect of all other implements of capital punishment is *precisely* the same, they would also be subject to FDA regulation under the parallel statutory definitions of "drugs" or "devices." Such a result would not only represent an insupportable extension of the nature and scope of FDCA regulation intended by Congress, see especially *Action on Smoking and Health v. Harris*, 655 F.2d 236, 240-41 (D.C. Cir. 1980), but it would entail an unprecedented intrusion on the states' powers to punish crime.

Requiring federal agents to seize and condemn the states' capital punishment apparatus, or to prosecute state officials for carrying out their duties to execute sentences, would constitute a harsh violation of the Tenth Amendment. Absent a judicial determination that a particular state action is unconstitutional, no branch of the federal government is authorized by the Constitution to interfere with the state's power to enforce the criminal law. There has been no adjudication that death sentences in the lethal injection states are unconstitutional; on the

contrary, they have been upheld under close Eighth amendment scrutiny.

This interference with state criminal law enforcement meets all elements for finding a Tenth Amendment violation under *Usery* and *Hodel*. The state is (1) regulated as a state (2) in a traditional sovereign function (3) which is integral to state government operations, and the federal intrusion is not remotely within the legitimate parameters of the Commerce Clause.

ARGUMENT

I. CHEMICALS USED BY STATES FOR THE INTENDED PURPOSE OF CARRYING OUT VALID CAPITAL PUNISHMENTS ARE NOT "DRUGS" UNDER THE FDCA AND THEREFORE THE FDA LACKS ALL JURISDICTION OVER THE MATTER

The Court below phrased its holding in terms which muted its potentially broad and drastic implications. The holding was presented in the relatively narrow perspective of whether the FDA erred in taking no regulatory action "against the unapproved use of *approved drugs* in state capital punishment systems." (Opin. p. 2; emphasis added).

What the Court studiously avoided discussing was the fundamental and novel premise that substances or articles used to implement capital punishment can be treated as "drugs" (or "devices") *at all* within the meaning of the FDCA. The Court assumed (without explanation) that they can, and proceeded to focus its attention on more specialized issues such as FDA policy regarding the use of "approved" drugs and FDA enforcement discretion.

As shown below, however, the substances at issue here do *not* constitute "drugs" in their specialized use by the states as implements of lawful execution. The courts

have established reasonable jurisdictional limitations, implicit in the statutory definition, which clearly preclude such an inapposite application of the FDCA. *Action on Smoking and Health v. Harris*, 655 F.2d 236, 240-41 (D.C. Cir. 1981) (cited hereafter as the *A.S.H.* case).

Moreover, had the Court expounded on the definitional issue, it would have been forced to reveal that the logic of its decision requires *all* implements of capital punishment to be regulated either as "drugs" or "devices" within the meaning of the FDCA. The parallel provisions of the Act's definitions of drugs and devices would compel this result. Since the various implements of capital punishment are all "intended to affect the . . . function of the body of man," 21 U.S.C. § 321(g)(1)(C), (h)(2), in the exact same way (i.e., cause death), either all or none are "drugs" or "devices" under the Act.

It follows that if lethal injection substances cannot be used for capital punishment until FDA has passed on their compliance with the Act's new drug and/or misbranding provisions, 21 U.S.C. §§ 352 and 355, then neither can the electric chair, the gas chamber, or any other implement of capital punishment.[1]

In short, affirmance of the D.C. Circuit's decision could enable opponents of capital punishment to obstruct *all* state executions which otherwise pass judicial muster under the Eighth Amendment because they have not met the administrative approval of the federal Food and Drug Administration. The D.C. Circuit's erroneous extension of the Act's jurisdiction would cast the FDA in

[1] Fourteen states authorize execution by lethal injection; sixteen by the electric chair; eight by the gas chamber; four by hanging; and two by firing squad. See *Civil Liberties*, Summer 1984, p. 10 (report of the American Civil Liberties Union's Capital Punishment Project). Various states provide for alternative methods. Some states—Montana, North Carolina, Utah, and Washington—allow the prisoner a choice between lethal injection and another means of execution.

the unconstitutional role of supervising the states' power to punish crime, in clear violation of the Tenth Amendment and the separation of powers doctrine.

A. The Court of Appeals Erred in Assuming that the Substances Could be Treated as "Drugs" in Their Distinct Use for Lawful Executions

Neither the panel nor the FDA focused attention on whether substances used for lethal injection in lawful state executions could rationally be classified as "drugs" *in connection with that particular use*. Instead, they took as a given that the substance's status as an "approved drug" for *other* uses satisfied the Act's definitional test. The issue was then reduced to whether a jurisdictional exception similar to that for physician's applied, or whether the requisite elements of "misbranding" were present. As a result, the decision never confronted—much less properly resolved—the genuine issue: *Does FDA jurisdiction over "drugs" and "devices" extend to regulating all the implements of execution used by the states under otherwise lawful capital punishment statutes?*

It is not the mere physical properties of a substance which render it a "drug" or "device" subject to FDA jurisdiction. Rather, as shown by the statute, the cases, and the FDA's own regulations, jurisdiction turns on the intended use of the item in the particular context in question. 21 U.S.C. §§ 321(g)(1)(B) and (h); *Kordel v. United States*, 335 U.S. 345 (1945); *United States v. Millpax, Inc.*, 313 F.2d 152 (7th Cir.), *cert. denied*, 373 U.S. 903 (1963); 21 C.F.R. § 201.28 (1983). Thus, the fact that the paralytics and barbiturates at issue had been classified as "approved drugs" in their more conventional usages as medicines does not establish their status as "drugs" when they are used by states as implements of capital punishment. It is that use *alone* which must be analyzed to determine if FDA jurisdiction applies in this case.

The definitions of the terms "drug" and "device" are set forth at 21 U.S.C. §§ 321(g) and (h). Subsection (g)(i)(A) of the "drug" definition includes "articles recognized in the official United States Pharmacopoeia." But the fact that the chemicals used for lethal injection may be listed in the U.S. Pharmacopoeia ("USP") does *not* in itself establish their status as drugs in that particular application. *National Nutritional Foods Ass'n v. Matthews*, 557 F.2d 325, 336-37 (2d Cir. 1977); *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir. 1974), *cert. denied*, 420 U.S. 946 (1975); *United States v. Goshen Laboratories*, [1982] Food Drug Cosm. L. Rep. (CCH) ¶ 38,174 (S.D.N.Y., May 28, 1982).

As stated by the Second Circuit in *National Nutritional Food Ass'n v. Matthews*, *supra*, 557 F.2d at 337:

> An administrator's decision under a regulatory statute, such as the Food, Drug, and Cosmetic Act, must be governed by an *intelligible statutory principle*. If § 201(g)(1)(A) defines as drugs every item included in the USP and NF, the FDA is not being consistent in its treatment of other items similarly recognized. The Commissioner, therefore, has not applied the Section 201(g)(1)(A) definition to every item in the compendia. Rather he has singled out for drug classification items included in the USP and NF on the basis of factors, such as toxicity in this case, that are not relevant to the statutory criteria in Section 201(g). [emphasis added; citations omitted].

These cases squarely hold that "mere inclusion of an item in the USP does *not* give the FDA the power to regulate that item as a drug," *United States v. Goshen Laboratories, Inc.*, *supra*, ¶ 38,174. [emphasis added]. To hold otherwise would vest the FDA with "virtually unlimited discretion to regulate as drugs a vast range of items." *National Nutritional Food Ass'n. v. Matthews*, *supra*, 557 F.2d at 337.

For purposes of this case, the most pertinent provisions of the FDCA's definitions of "drugs" and "devices" are those set forth at 21 U.S.C. §§ 321(g)(1)(C) (drugs) and (h)(2) (devices). A "drug" includes

> . . . (c) articles (other than food) *intended to affect* the structure or *any function of the body of man* or other animals; . . . .

A "device" includes

> . . . instruments, apparatus, and contrivances, including their components, parts, and accessories, *intended* . . . (2) *to affect* the structure or *any function of the body of man* or other animals. [emphasis added]

If the substances at issue are to be treated as "drugs" when used by the states for lawful executions, it is because their use in *that* context "affect[s] any function of the body of man" in a manner which falls within the FDCA's intended coverage, *A.S.H.*, *supra*, 655 F.2d at 241. That determination does not turn on their intended uses in other contexts. The fact that barbiturates and paralytics happen to be "approved drugs" for wholly different applications therefore affords no basis for distinguishing them from any other substance or article which is intended to "affect the functions of the body of man" in the same way—i.e., to cause death by execution. The only apparent distinction is whether other execution methods would be regulated as "drugs" (e.g., the gasses used by some states) or "devices" (electric chairs, gallows, and rifles and bullets). Only those that constitute "drugs" (gasses and injections) would be required to meet the "new drug" approval requirements of FDA, 21 U.S.C. § 355, but *all* implements of execution, whether drugs or devices, would be required to meet the "misbranding" provisions invoked by the D.C. Circuit to invalidate the use of lethal injections, 21 U.S.C. § 352.[2]

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[2] Even capital punishment apparatus which would be classifiable as a "device" rather than a "drug" would be subject to the rigorous

Thus, the validity of the decision below ultimately rests on a hyper-literal interpretation of the Act which would subject all methods of capital punishment to FDA jurisdiction under the "misbranding" provisions and the drug and device approval procedures. Since *no* method of execution has established compliance with any of those provisions, the enforcement theory adopted by the court below would inevitably result in a nationwide stay of executions pending satisfaction of all FDA requirements. Those requirements are wholly inapposite to subetances or articles used to cause death by execution (i.e., the standard of "safe and effective" for new drug approval, 21 U.S.C. § 355) and compliance with them simply could not be proven.

B. Well-Established Limitations on FDA Jurisdiction Exclude the Implements of Capital Punishment from Drug and Device Regulation

The D.C. Circuit erred in failing to recognize (1) that substances treated as "approved drugs" in one context may not constitute drugs *at all* when used for entirely different purposes; and (2) that there are implicit (not to mention *constitutional*) limitations on the literal reach of FDA jurisdiction which are derived from the functional objectives of the Food, Drug, and Cosmetic Act. Proper application of those well-settled precepts demonstrates the fatal flaws in the panel's overreaching decision.

Numerous cases establish the proposition that an item's status as a "drug" under the Act depends upon the particular intended use under consideration, and whether that use falls within the particular purposes of the FDCA.

Thus, the Courts have held that even honey and cigarettes could be treated as "drugs" in circumstances where

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"premarket approval" requirements set forth at 21 U.S.C. § 360e. Such premarket approvals also require demonstration that the device is "safe and effective", 21 U.S.C. § 360e(c)(A).

they were shipped with leaflets claiming various health benefits associated with their use. See *United States v. 46 Cartons*, 113 F. Supp. 336 (D.N.J. 1953); *United States v. 250 Jars of Fancy Pure Honey*, 218 F. Supp. 208 (D. Mich. 1963), *aff'd*, 344 F.2d 288 (6th Cir. 1964). Such cases represent reasonable application of the Act's objective to reach even items not commonly regarded as drugs or medicines whenever they are *marketed* on the strength of their claimed *health benefits*.

The specific purpose of subsection 321(g)(1)(C) of the "drug" definition—i.e., the provision encompassing articles "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C)—was to extend regulation to such products "that have been found *on the market* that cannot be alleged to be treatments for diseased conditions." *Food, Drugs, and Cosmetics: Hearings on S.1944 before Subcomm. of Senate Comm. on Commerce*, 73d Cong., 2d Sess. 15-16 (1933) (Statement of Walter G. Campbell, Chief of FDA). The critical distinction between the items intended to be covered by subsection 321(g)(1)(C)—such as fraudulent "anti-fat" remedies—and the implements of lawful execution is that the latter are not marketed to consumers on the basis of claims concerning health or therapeutic benefits.

The most pertinent decision to the issue at hand was provided by the D.C. Circuit itself in the *A.S.H.* case, *supra*. There, it was held that cigarettes which are not marketed with representation of beneficial health qualities do *not* constitute drugs within the meaning of the FDCA. Recognizing that cigarettes could be said "to affect the structure or any function of the body of man" (thus literally meeting the statutory definition of "drugs" or "devices"), the Court approvingly quoted from *FTC v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573, 576 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953) as follows (655 F.2d at 240):

> Anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently, any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the senses may be said to be an article "intended to affect the functions of the body of man" . . .
>
> *Surely, the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be.* [emphasis added]

Judge Tamm's opinion went on to posit further examples demonstrating the pitfalls of rigid literalism in applying the FDCA's definitions of drugs and devices. Perhaps most pertinent was its reference to 1969 Congressional testimony given by the Department of Health, Education, and Welfare, stating the Administration's position that protective chemical sprays (such as "mace") could not be classified as "drugs" under the FDCA. As the Court approvingly quoted that testimony (655 F.2d at 240):

> I suppose that *pistols and bullets* are intended to affect the function or structure of the body in the same way these are, but we concluded that the products could not properly be classified as drugs under the definition in the Food, Drug, and Cosmetic Act. [emphasis added]

The Court proceeded to hold that such commonsense limitations are "implicit in the statutory definition of a drug," 655 F.2d at 241, and more than justified the FDA's disclaimer of jurisdiction over cigarettes.

The D.C. Circuit's sensible analysis in the *A.S.H.* case fatally undercuts the holding of a single member of their brethren in this case.[3] The *A.S.H.* panel explicitly recog-

[3] The D.C. Circuit panel's decision in the *A.S.H.* case was unanimous (Tamm, Robb, and Mikva, J.J.). In the instant case, the two actual members of the Circuit on the panel (Wright and Scalia, J.J.) reached directly opposite conclusions. Judge Wright's opinion

nized that things like "mace", pistols and bullets could not be properly regulated as "drugs" or "devices" by FDA, even though they are "intended to affect [a] function of the body of man." Such items are not marketed or promoted for their health-promoting or therapeutic qualities, and are self-evidently beyond the intended objectives of the Food, Drug, and Cosmetic Act. The very same reasoning applies to electric chairs, gallows, and gas chambers, which obviously fall outside "the limitations implicit in the statutory definition of a drug," *A.S.H.*, 655 F.2d at 241. And if the foregoing implements of execution are not covered by the Act, it is anomalous to hold that lethal injection substances are covered merely because they happen to be "approved drugs" for discrete medicinal uses having nothing to do with execution.

It is ironic that the same court which upheld the FDA in disclaiming jurisdiction over cigarettes now insists that FDA is compelled by "public health" imperatives to regulate the implements of capital punishment as drugs. In the instant case, the Court found FDA's refusal to take jurisdiction especially insupportable because—according to the Court—the use of lethal injections for capital punishment "certainly" poses a serious danger to the public health. (Op. at p. 34). But whatever alleged dangers to the "public" health might be raised by using lethal injections as an alternative means of lawful execution[4] pale to insignificance in comparison to the dangers

carried the day only on the vote of a District Judge from the Northern District of California who was sitting by designation under 28 U.S.C. § 294(d). Circuit Judges Wilkey, Ginsburg, Bork, Scalia, and Starr all would have granted *en banc* rehearing.

[4] It is difficult to find any legitimacy in the panel's assertion of a "serious danger to the public health" raised by use of lethal injection. Prohibiting use of lethal injection will only relegate condemned men to alternative methods of execution—e.g., hanging in Montana and Washington, or the firing squad in Utah—which many people would regard as more painful and traumatic. Far from serving "humane" objectives, the panel's decision would cruelly de-

caused by cigarettes to the health of tens of millions of Americans. Notwithstanding the compelling public health hazards raised by cigarette smoking, the D.C. Circuit properly declined to distort FDA drug jurisdiction to include cigarettes in the *A.S.H.* case. Since the public health predicate for asserting jurisdiction is not nearly as significant in this case, the panel's anomalous and revolutionary expansion of federal drug regulation is all the more insupportable.[5]

In this connection, any reliance on the unreported and highly questionable decision in *United States v. Beauthanasia D. Regular*, [1979 Transfer Binder] Food, Drug, Cosm. L. Rep. (CCH) ¶ 38265 (D. Neb. 1979) is wholly unwarranted. There, the District Court held that animal euthanasia constitutes "an effect on the structure and function of the body" falling within the definition of drugs insofar as it applies to animals. Aside from being wrongly decided, *Beauthanasia* is plainly distinguishable from this case. Not only were the substances used there affirmatively marketed by their manufacturers for the purpose of animal euthanasia, but the very nature of the latter procedure is fundamentally different from lawful capital punishment. While animal euthanasia is an elective procedure performed on innocent creatures, capital punishment is a mandatory duty of the state required

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prive condemned men of their statutory option to select a far less traumatic means of execution. Only if the D.C. Circuit's decision bars *all* forms of capital punishment will it achieve the "humanitarian" objectives presumably intended by its authors.

[5] If the decision here is affirmed, it would also appear that items such as mace and ammunition used in law enforcement would now require FDA regulation as drugs or devices, respectively. They are intended to affect a function of the body of man, and have a far broader quantitative impact on the "health" of people than the implements of capital punishment. If FDA is required by the Act to assure the minimization of pain for convicted capital felons, it follows *a fortiori* that such mandatory protective regulation would extend to unconvicted persons who will be maced or shot in connection with law enforcement operations.

by law to punish duly convicted murderers. Moreover, the potential for arbitrary and unnecessary pain in state executions is already subject to adequate safeguards provided by the courts under the Eighth Amendment. That one bizarre construction of the Act has forced FDA to regulate animal euthanasia hardly provides justification for a far more radical distortion of the Act which would undermine the integrity of state law enforcement.

II. IF THE FDA EXERCISED THE POWER IMPOSED ON IT BY THE COURT BELOW IT WOULD VIOLATE THE TENTH AMENDMENT

Among the numerous flaws in the majority decision raised by Judge Scalia's dissent is that it mandates "a clear intrusion upon powers that belong to . . . the states." (Dissenting Op., p. 1). More specifically, implementation of the decision would create a violation of the Tenth Amendment to the Constitution, which provides:

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

The decision below violates the Tenth Amendment by forcing the FDA to obstruct the states in their implementation of sentences authorized by constitutional capital punishment laws. This Tenth Amendment violation is especially unsettling, because the federal government itself disavows the legitimacy and necessity of the federal intrusion.[6]

Absent a judicial determination that a state criminal penalty is unconstitutional (*Cf. EEOC v. Wyoming*, 75 L. Ed. 2d 18, 38-47 (1983) (Burger, C.J., dissenting),

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[6] The Government Petitioner has not directly posed the Tenth Amendment issue as such, possibly out of concern for its prerogatives in other fields of regulation. But *amicus* notes that the *certiorari* petition tacitly recognizes the Tenth Amendment violation in stating that the decision below "unjustifiably interferes with the states' lawful exercise of their power to enforce their criminal laws". Petition for Certiorari at p. 7.

the Constitution nowhere delegates to any federal branch the power to interfere with a state's enforcement of its criminal sanctions. As stated by this Court in *Screws v. United States*, 325 U.S. 91, 109 (1945):

> The Fourteenth Amendment did not alter the basic relations between the states and the national government. . . . Our national government is one of delegated powers alone. *Under our federal system, the administration of criminal justice rests with the states* except as Congress, acting within the scope of its delegated powers, has created offenses against the United States. [emphasis added].

The state's power in the field of crime and punishment lies at the very heart of the "integral functions" of state government which the Tenth Amendment carefully preserved from officious federal intrusion. See *National League of Cities v. Usery*, 426 U.S. 833, 851 n.16 (1976). The Interstate Commerce Clause, Art. I, § 8, cl. 3, hardly gives Congress the power to assume supervision of state criminal punishment methods—least of all where the Commerce objective is an obvious pretext for interference with state law enforcement.

Following this Court's decision in *Usery*, *supra*, recent federal decisions have shown increased sensitivity to valid Tenth Amendment considerations, particularly in relation to unfettered federal encroachment under the Commerce power. *E.g.*, *United States v. Onslow County Board of Education*, 728 F.2d 628, 640 n.9 (4th Cir. 1984); *United States v. Best*, 573 F.2d 1095, 1102 (9th Cir. 1978); *Davids v. Akers*, 549 F.2d 120, 127 (9th Cir. 1977); *Peel v. Florida Dept. of Transportation*, 600 F.2d 1070, 1082-85 (5th Cir. 1979); *San Antonio Metropolitan Transit Authority v. Donovan*, 557 F. Supp. 445 (W.D. Tex. 1983), *appeal pending* (5th Cir. 1984). This approach involves genuine scrutiny of the legitimacy of the federal intrusion under the Commerce Clause, rather than mechanical subordination to it. If the asserted rationale for Commerce Clause regulation is a mere pretext for an otherwise invalid encroachment on state powers, or if the

nexus to the claimed Commerce power is insubstantial, then the Tenth Amendment requirements prevail. As the Fifth Circuit described this approach in *Peel v. Florida D.O.T.*, *supra*, 600 F.2d at 1085:

> . . . [B]y weighing the *legitimate* exercise of Congressional power against the intrusion into areas of state sovereignty, the Courts have determined whether the 10th Amendment prevents Congressional action. [emphasis added]

Applying that balancing test to the case at hand, it becomes clear that the states' residual Tenth Amendment powers would be violated by the D.C. Circuit's extraordinary extension of FDA regulation.

Here, any Commerce Clause justification for Congressional regulation of executions is extremely precarious, if not duplicitous; the state's implementation of its capital punishment laws hardly constitutes a genuine problem concerning interstate commerce in drugs, or a broad "public health" concern. Rather, it is obvious that the panel is attempting to charge the FDA with duties akin to those of a "special master" or expert witness in connection with Eighth Amendment challenges to the various implements of capital punishment[7]—all under the transparent guise of the Commerce Clause. Meanwhile, the FDA insists that its power to regulate drugs does *not* reach the implements of lawful capital punishment used by the States. A more egregious example of unconstitutional arrogation of power by the judiciary could hardly be imagined. The FDA simply is not empowered by Congress to assist convicted criminals in their attempts to avoid their sentences.

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[7] This purpose is revealed in the following language from the Court's opinion (p. 38):

> As a result of the FDA's inaction, appellants face the risk of a cruel execution and are deprived of the FDA's expert judgment as to the effectiveness of the drugs used for lethal injection, the latter fact making any direct challenge they might bring to this method of execution more difficult.

Significantly, Tenth Amendment jurisprudence recognizes that *judicial* orders directing unwarranted federal interference with sovereign state power can violate the Tenth Amendment no less than invalid legislation. *United States v. Best*, *supra*, 573 F.2d at 1102; *Davids v. Akers*, *supra*, 549 F.2d at 127. Here, the D.C. Circuit's bizarre extension of the FDCA would deprive the states of their power to implement capital punishment sentences already upheld by the courts under Eighth Amendment standards. *E.g.*, *Ex Parte Granviel*, 561 S.W.2d 503 (Tex. Cr. App. 1978); *O'Bryan v. McKaskle*, 729 F.2d 991 (5th Cir. 1984); *Gray v. Lucas*, 710 F.2d 1048 (5th Cir. 1983). Ignoring the separation of powers doctine as well, the court below would superimpose the FDA's standards for passing on the safety and efficacy of drugs upon the constitutional standards applied by courts *alone* under the Eighth Amendment.

The regulatory invasion ordered by the D.C. Circuit meets all the criteria for holding federal action in violation of the Tenth Amendment. Those three criteria were set forth by this Court in *Hodel v. Virginia Surface Mining and Reclamation Ass'n*, 452 U.S. 264 (1981), as follows:

1. *The challenged measure must regulate the state as a state.* This criterion is indisputably satisfied. Under the broad theory of FDCA jurisdiction approved by the D.C. Circuit, state correctional officials would be subject to federal criminal prosecution for carrying out their official duties, and the state's capital punishment apparatus would be subject to condemnation and seizure by federal authorities. Indeed, that is precisely the form of relief sought by the plaintiffs in this and related cases. *E.g.*, *O'Bryan v. Heckler*, No. A-791 (5th Cir., Mar. 30, 1984).

2. *It must affect matters of indisputable state sovereignty.* The power to enforce the criminal law through appropriate penalties lies at the very heart of residual state sovereignty. See *Usery*, *supra*, 426 U.S. at 851 n.16

and 852. If the states' power to punish crimes is held hostage to the vagaries of federal bureaucratic clearances, they would cease to be sovereign states as we know them.

3. *Compliance with the federal regulation must directly impair the state's ability to maintain "integral operations in areas of traditional [state] governmental function."* There can be no question that the imposition of punishment for crimes is in the area of "traditional state government functions." It is perhaps the *most* traditional of state functions. Nor can there be any doubt that subjecting the implements of capital punishment to the new drug approval and misbranding provisions of the FDCA would directly impair the state's ability to carry out this integral function. It is extremely doubtful that *any* method of execution could be satisfactorily established as "safe and effective" under existing FDA requirements (See 21 U.S.C. §§ 355 and 360e(c)(A)). Most obviously, it would be impossible to conduct the necessary testing needed to establish whether or not a particular method was less painful than another in actual practice. It is also most doubtful that any drug company would be willing to go to the expense of seeking "new drug" approval for an application of such limited marketability. Further, the misbranding requirements for adequate warnings "against unsafe dosage or methods or duration of administration or application," 21 U.S.C. § 352(f)(2), would seem to preclude compliance in the case of drugs or devices used for executions. There would again be no feasible means to test for compliance.[8]

Thus, enforcement of the FDCA's new drug and misbranding provisions against the states' methods of execution would offend all three of the federalist principles

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[8] What the D.C. Circuit observed with respect to cigarettes in the *A.S.H.* case is probably applicable here as well (655 F.2d at 241):

> Indeed, if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended us [sic].

used to determine a Tenth Amendment violation under *Hodel*.

It is most revealing that even the FDA—the agency commissioned by Congress to police commerce in drugs to the full extent allowed by federal law—has prudently determined that the policies of the FDCA have no proper application to the states' methods of imposing lawful capital punishment. Nothing in the Act's legislative history remotely suggests that Congress intended federal drug regulation to intrude in that area of traditional state sovereignty. It is only the subjective policy preferences of two federal judges which have forced this unprecedented collision between the Congressional Commerce Power and the state's Tenth Amendment power to punish crimes. *Compare Davids v. Akers*, *supra* 549 F.2d at 127.

Since Congress and the FDA have declined to warp federal drug regulation to fit the incompatible contours of state capital punishment practices, there is no constitutional basis for a federal court to do so. The Court of Appeals' decision thus entails a serious violation of the Tenth Amendment by interfering with sovereign state power in a manner never authorized by Congress or contemplated by the Constitution.

CONCLUSION

The D.C. Circuit's decision in this case represents a radical and insupportable departure from well-established principles of statutory and constitutional law. It distorts the intended coverage of federal drug regulation in order to create a bizarre new vehicle for collateral challenge to capital sentences. And it violates the Tenth Amendment by forcing a reluctant federal government to interfere with the states' sovereign powers to enforce the criminal law. The decision should be reversed.

Respectfully submitted,

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AMICUS CURIAE

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IN THE

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OCTOBER TERM, 1984

MARGARET M. HECKLER,
SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

LARRY LEON CHANEY, *et al.*
Respondents.

**ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

BRIEF OF *AMICUS CURIAE* PUBLIC CITIZEN URGING THE COURT TO AFFIRM THE DECISION OF THE COURT OF APPEALS

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INTEREST OF *AMICUS CURIAE*

Amicus Curiae Public Citizen is a broad based consumer organization whose interests will be directly and adversely affected if the government's position in this case is upheld by the Court. Accordingly, on behalf of its over 40,000 contributors, Public Citizen respectfully urges that the judgment below be affirmed and that the case be remanded to the Food and Drug Administration ("FDA") for proceedings consistent with the Court of Appeals' rul-

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*This brief is filed with the written consent of all parties, copies of which are on file with the Court.

ing that the FDA has jurisdiction to regulate lethal injections.

Public Citizen has filed numerous lawsuits challenging decisions by federal agencies not to exercise their statutory authority in particular ways. *See, e.g., Bargmann v. Helms,* 715 F.2d 638 (D.C. Cir. 1983); *Public Citizen Health Research Group v. Auchter,* 702 F.2d 1150 (D.C. Cir. 1983). Moreover, Public Citizen and its affiliates have brought many cases against the FDA seeking judicial review of the agency's declinations to enforce the Food, Drug and Cosmetic Act in specific circumstances. *See, e.g., Public Citizen Health Research Group v. Hayes,* No. 83-1302 (D.C. Cir. July 27, 1984); *McIlwain v. Hayes,* 690 F.2d 1041 (D.C. Cir. 1982); *Cutler v. Kennedy,* 475 F. Supp. 838 (D.D.C. 1979); *American Public Health Association v. Venemen,* 349 F. Supp. 1311 (D.D.C. 1972). Accordingly, Public Citizen has a significant stake in any ruling by this Court regarding the scope of judicial review of agency enforcement decisions in general and FDA enforcement decisions in particular. Indeed, if the government's position in this case is sustained, it could insulate from judicial review an extraordinary range of agency enforcement decisions that Public Citizen has regularly — and often successfully — challenged in the past.

ARGUMENT

This action involves a challenge to a refusal of the Food and Drug Administration to respond affirmatively to the citizens' petitions filed by respondents, which asked the agency to enforce the safety and efficacy requirements of the Food, Drug and Cosmetic Act ("FDC Act") as they apply to lethal injections of drugs used by 15 states to implement the death sentence. With their petitions, respondents submitted substantial evidence that the drugs cur-

rently in use for such purposes cause excruciating pain prior to death and hence are not safe and effective for that use as required by the FDC Act, 21 U.S.C. § 342.

In response, FDA admitted that the drugs had not been approved for executions, but claimed that it lacked jurisdiction to regulate the use of drugs to execute those sentenced to death. As an afterthought, it added a paragraph suggesting that even if it had authority under the law, it would exercise its discretion not to initiate regulatory action. The only rationale articulated by FDA for its refusal to enforce the FDC Act as requested by respondents was that "enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions." Pet. App. 85a. In other words, the agency's sole reason for not exercising its enforcement authority was simply a reformulation of its primary determination that it lacked statutory authority to act.

All three judges in the Court of Appeals agreed that the FDA was in error in its contention that it lacked jurisdiction. Although petitioner does not argue in this Court that the Court of Appeals was in error on the underlying jurisdictional point, she nonetheless contends that judicial review of every FDA decision not to enforce the law is barred, regardless of how sweeping or ill-considered it may be.

The principal flaw in petitioner's argument is the assumption that all decisions to decline to enforce a provision of law are treated identically for purposes of the Administrative Procedure Act. That kind of equal treatment

would be no more appropriate than it would be for a court to apply the same standard of review to all agency decisions, regardless of whether they are based on interpretations of law, findings of fact, or pure policy considerations. Likewise, in the area of agencies' refusals to take enforcement actions, differing standards apply depending on the basis on which the agency declined to take the requested enforcement action. In fact, numerous judicial decisions demonstrate that the reviewability of a decision not to enforce a provision of law depends on various factors, including the type of enforcement decision at issue and the rationale for the decision.

Where, as here, an agency refused to act because it incorrectly interpreted the FDC Act or its jurisdiction, then the question on review is purely one of law as to which ordinary principles of administrative law and statutory interpretation apply, and there is no reason for the court not to decide those questions. *See, e.g., Bargmann v. Helms,* 715 F.2d 638 (D.C. Cir. 1983). Similarly, if an agency refused to enforce an entire portion of its operative statute because, for instance, it disagreed with Congress' purpose, surely no court would be disabled from examining the propriety of that refusal. *See Adams v. Richardson,* 480 F.2d 1159 (D.C. Cir. 1978). Yet petitioner's arguments necessarily lead to the conclusion that the FDA could decline to take enforcement action against whole categories of ineffective drugs based on a misinterpretation of or disagreement with the FDC Act, and that such a decision would be entirely shielded from judicial review.

On the other end of the spectrum, if a petition for agency action were rejected because the alleged violation was isolated and technical, and the agency was occupied with more pressing activities involving serious injuries to the public, a court would be appropriately reluctant to second

guess the agency determination. Indeed, such reluctance is similar to that shown by the courts in declining to interfere with decisions not to prosecute certain criminal activities. Thus, as a request for action becomes increasingly narrow and fact-specific, the greater is the propriety of courts simply refusing to become enmeshed in the controversy. In this case, because the refusal to act was so clearly based on a construction of law, the entire discussion in petitioner's brief dealing with interference with prosecutorial decisions has no bearing whatsoever.

Petitioner also argues in this Court that the FDA's decision can be defended on a number of other grounds beyond the jurisdictional argument which it has abandoned. That position cannot be sustained because it violates a fundamental principle of administrative law. As this Court decided in *SEC v. Chenery Corp.,* 318 U.S. 86 (1943), an agency's decision can be defended in court only on the grounds actually relied on by the agency at the time of its decision and cannot be upheld based on the *post hoc* arguments of counsel. That principle applies with particular force in this case where the arguments that are now advanced to justify the refusal to act were not even presented in the District Court or the Court of Appeals. Accordingly, for this reason alone, the Court should affirm the ruling of the Court of Appeals that the FDA erroneously based its decision not to take enforcement action on a misinterpretation of its jurisdiction, and remand the remaining questions to the agency for further consideration. Only after the agency itself considers the matter would judicial review of these other reasons be appropriate.

Petitioner also argues that the alternative reason that FDA actually stated in denying respondents' petition — that it would exercise discretion not to take the requested action in any event — is an independent basis for entering

judgment in the FDA's favor. That claim is in error for several reasons. First, as is apparent from reading that portion of the agency's decision, the reason offered is plainly an afterthought, a throw-in suggested just in case the principal basis was not sustained. Indeed, the agency's proffered rationale for not exercising its enforement discretion, while ambiguous, apparently constituted only a restatement of its jurisdictional finding.

At a minimum, it is clear that the decision not to act was significantly influenced by the agency's view on the jurisdictional question. Thus, there is no basis for believing that the agency gave the matter a "hard look" after finding that it had no jurisdiction, thus making it singularly inappropriate for the Court to affirm on that basis. Further, the agency's refusal to reply to respondents' evidence is a further indication that it did not give the question the kind of consideration needed to sustain its ruling. Similarly, the FDA failed to offer any evidence of its own to support its claim that the problem of lethal injections was not serious and that it was too busy with other matters to fully respond to the petition.

This brings us to another error in petitioner's analysis. The propriety of judicial intervention in an agency's refusal to act is significantly affected by the nature of the relief requested. Thus, for example, a petition which asked the agency to seize all lethal drugs earmarked for executions that are now on the market, might properly be denied on grounds of lack of enforcement capability. In contrast, a request that the FDA merely issue a rule or policy statement that it was unlawful to use such drugs for such purposes without an approved new drug application could not validly be denied on resource allocation grounds. In the latter situation, it is entirely likely that the persons affected would voluntarily comply with the ruling, particularly where, as here, they are state agencies and not private individuals. Yet despite these obvious differences between types of potential relief, and hence the propriety of judicial intervention, petitioner seeks to cloak all FDA actions with the mantle of prosecutorial discretion, wholly exempt from judicial review.

There is another real danger that would flow from allowing the FDA to rely on its sweeping, conclusory claim of enforcement discretion as a basis for avoiding any judicial review of its denial of the petition. The type of vague generalities offered by the FDA here could be used to support almost any failure to act, no matter how clear the agency's actual, improper motives may have been. Surely, this Court did not permit judicial review of the Secretary of Labor's refusal to overturn a union election in *Dunlop v. Bachowski*, 421 U.S. 560 (1975), simply because the agency did not include the open-ended boilerplate on which petitioner relies here. Stated another way, by permitting the FDA to defend its own improper decisions on these grounds would be a license to all agencies to refuse to act for any reason, no matter how improper, so long as the "enforcement discretion" boilerplate was added at the end of the rejection of the petition.

CONCLUSION

In the instant case, the principal, if not sole, reason that the FDA rejected respondents' request was that it believed it lacked jurisdiction. That purely legal issue was properly the subject of judicial review, and the Court of Appeals correctly resolved the question. Having decided the principal legal issue, at that point it was proper to remand the matter to the agency for such further action as might be

appropriate, including further consideration of the petition and possible rejection of it on grounds not previously relied on. But the propriety of relying on such alternative grounds is not an issue before this Court because they were not raised by the agency at the time of the rejection or in either of the courts below. Therefore, the decision of the Court of Appeals reversing the District Court's approval of the rejection of the petition should be affirmed, and the case remanded to the agency for further proceedings consistent with the jurisdictional ruling of the Court of Appeals.

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Respondents.

On Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF THE AMERICAN SOCIETY OF LAW AND MEDICINE, THE AMERICAN SOCIETY OF ALLIED HEALTH PROFESSIONS, DR. DAVID J. ROTHMAN AND DR. EDMUND D. PELLEGRINO AS AMICI CURIAE SUPPORTING RESPONDENTS

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BRIEF OF AMICI CURIAE, AMERICAN SOCIETY OF LAW AND MEDICINE, AMERICAN SOCIETY OF ALLIED HEALTH PROFESSIONS, DR. DAVID J. ROTHMAN AND DR. EDMUND PELLEGRINCO

ISSUES PRESENTED

Amici will address the following issue:

WHETHER THE COURT OF APPEALS CORRECTLY CONCLUDED THAT THE FOOD AND DRUG ADMINISTRATION, BY FAILING TO INVESTIGATE THE DRUGS USED IN LETHAL INJECTION EXECUTIONS ARBITRARILY ABNEGATED ITS ADMINISTRATIVE RESPONSIBILITY.

INTEREST OF AMICI

Amici are individuals and organizations with interest and expertise in the ethical and social implications of using lethal injection as a method of execution. The American Society of Law and Medicine is the nation's largest multidisciplinary organization dedicated to providing a forum for the discussion of current issues in the fields of medicine, law, and health care. On behalf of a membership of physicians, dentists, nurses and other health care professionals, lawyers, judges, insurance company officials, health administrators, and educators, it examines ethical, social and legal issues through journals, conferences, and working groups. The American Society of Allied Health Professions is a non-profit

professional organization whose membership consists of educational institutions, professional organizations, clinical services, and individuals devoted to allied health education, research, and service delivery. Since its incorporation in 1967, ASAHP has been committed to addressing the critical issues affecting allied health education, including health care legislation, manpower needs, personnel preparation and utilization, accreditation and professional standards of practice, and technological advances in the health care field. Along with over 1,300 individual members, the Society serves and represents a constituency of 20 professional organizations (whose members total approximately 310,000 professionals in related services), and

120 collegiate schools of Allied Health, containing close to 1,000 Allied Health educational programs and graduating approximately 36,500 professionals each year. Edmund D. Pellegrino, M.D., Professor of Medicine, Georgetown University Medical Center is Director of the Kennedy Institute of Ethics, the leading academic center for the study of ethical issues in biomedical research and practice. David J. Rothman, Ph.D., Bernard Schoenberg Professor of Social Medicine, at the College of Physicians and Surgeons of Columbia University is the Director of the Center for the Study of Society and Medicine, a leading center for the study of the social implications of medical theory and practice.

The interests of amici converge

on the use of drug injections -- until now an exclusively medical practice -- to accomplish executions.

Amici have obtained and lodged with the Court the written consent of the parties to file a brief in this case.

SUMMARY OF ARGUMENT

The Brief for the Petitioner maintains that the relief ordered by the Court of Appeals logically requires that the FDA assert jurisdiction over gas chambers, gallows, and electric chairs, since as "drugs" and "devices" they are indistinguishable from lethal injections. Brief for Pet. at 44. See also Brief for Washington Legal Foundation, Amicus Curiae, at 5-10.

No argument could be further from

the point. The significance of the lethal injection method of execution, for both its proponents and its opponents, lies not in the ways in which it resembles the gallows and the firing squad but in the ways in which it resembles the events at the heart of the FDA's jurisdiction: the antiseptic, medical application of drugs. The legislators based their actions on the belief, echoed by Judge Scalia, that they were substituting, "(I)n all likelihood ... a lesser pain." Chaney v. Heckler, 718 F.2d 1174, 1199-1200 (D.C. Cir. 1983) (Dissenting opinion of Scalia, J.), Pet. App. at 51n.

Although this case was decided on summary judgment, the record presents uncontroverted proof that lethal injection legislation is premised on an

illusion. The drugs employed have not been tested for this new use. Moreover, medical professionals will not lend themselves to a procedure that ignores the distinction between healing and killing. In the absence of FDA inquiry into the safety and efficacy of these drugs and procedures when not administered by physicians, hundreds of people may be subjected to thoroughly amateur poisonings rather than to the painless and dignified executions envisioned by the legislators.

Amici contend that the Agency's refusal to conduct even a cursory exploration of the potentially horrifying consequences of execution by lethal injection represents an arbitrary abnegation of the Agency's responsibility. The Court of Appeals has merely

ordered that the Agency fulfill its statutory function by investigating whether use of drugs for lethal injection without warning constitutes a misbranding in violation of 21 U.S.C. §352(f). Without prejudging the outcome of such an FDA inquiry, amici believe that it is required by the statutory framework and the gravity of the danger.

ARGUMENT

I

THE RISK OF PAINFUL AND INEFFECTIVE ADMINISTRATION OF LETHAL INJECTIONS IS INCREASED BECAUSE HEALTH CARE PROFESSIONALS' ETHICAL STANDARDS PRECLUDE THEIR PARTICIPATING IN EXECUTIONS

A) The Use Of The Drugs for Lethal Injection Is Not Based On Adequate And Well Controlled Investigations

While proponents of the lethal injection method have advanced a variety of practical arguments in favor of its use -- they assert that lethal injections are cheaper than conventional executions,[1] more seemly to witness,[2] and more likely to appeal to jurors[3] -- it is plain that these considerations are subsidiary to the main impetus for the enactment by several states of lethal injection legislation. The primary reason for the enactment of these laws was legislators' belief that

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1 P. Malone, Death Row and the Medical Model, HASTINGS CENTER REPORT, p. 5 (October 1979).

2 See, e.g., Christianson, Corrections Law Developments: Execution by Lethal Injection, 15 CRIM.L.BULL., 69, 73 (1979).

3 P. Malone, supra, at 5.

death by lethal injection is more humane and more dignified than death by electrocution, hanging, or the gas chamber. See Note, Capital Punishment-Texas Statutes Amended to Provide for Execution by Intravenous Injection of A Lethal Substance, 9 ST. MARY'S L.J. 359, 361 (1977). Repulsive tales of botched hangings and faulty electric chairs abounded, and even when the older methods were faultlessly employed the consequences were grisly to witness. Gardner, Executions and Indignities -- An Eighth Amendment Assessment of Methods of Inflicting Captial Punishment, 39 OHIO ST. L.J. 96, 118-128 (1978). An understandable desire grew for a method of execution in which the prisoner would "go to sleep" with "little more indignity than attends an

ordinary surgical operation." Gardner, supra, 39 OHIO ST. L.J. at 129. Routine medical experience, particularly experience with drugs which are used to stop the heart during surgery (while a patient is supported by a respirator), seemed to promise a solution.

Unfortunately, as shown by recognized authorities in anesthesiology, there are "no published scientific data or information which in any respect address the use of sodium thiopental, tubocuraarine, potassium chloride, succinycholine, or any other drugs as a means of execution or which establish their effectiveness for a quick, painless execution." Affidavits of Dr. Leroy Vandam (J.A. at 78) and Dr. Richard Hodes (J.A. at 69). The drugs chosen for executions, in other words,

have been chosen by a process of educated guess rather than by an assessment of, "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." 21 U.S.C. §355(d). Individual responses to the designated drugs are known to vary and it is impossible to be assured that the prisoner would not be conscious of suffocation. Affidavit of Dr. Hodes, J.A. at 70. The difficulties created by lack of knowledge of the effects produced by using these drugs for this purpose, pale beside the difficulties of administering them.

B) <u>The Danger Of The Drugs' Use Is Increased By The Justifiable Refusal Of Health Care Professionals To Participate In Executions</u>

1. <u>Specialized Knowledge and Training Are Needed To Administer The Drugs In An Approved Manner</u>

Nothing in the record disputes the respondent's claim that the technique of intravenous injection is fraught with dangers. It is extremely difficult, if not impossible, to give lethal injections to persons with certain common physical conditions and abnormalities. Royal Commission on Capital Punishment Report 1949-1953 (1953), J.A. at 37-40. Moreover, even people without abnormalities experience some constriction of the veins in anticipation of intravenous injections. It is expected that prisoners facing

execution will manifest similar reactions, magnifying the difficulty of achieving effective venipuncture. Even when the needle is finally within a vein the drug may escape into the surrounding tissue, causing severe pain. J.A. at 41.

The risks of an agonizing dying process, or even of failure of an injection to be lethal, are exacerbated when trained personnel are unavailable to perform the injections. Affidavit of Richard Hodes, M.D., J.A. at 70-71. At present there is no reason to believe that adequately prepared individuals will be involved in the executions. Indeed, the evidence strongly suggests that this delicate medical procedure will be handled in a thoroughly amateur fashion with appalling results.

2. Health Care Professionals' Refusal To Participate In Lethal Injections Has A Weighty Ethical Basis

The medical community holds no uniform view for or against capital punishment as a general matter. Nor would medical participation in a search for a humane method of execution be a novel phenomenon. The guillotine was invented by a doctor appalled by hangings; a 19th century commission of physicians in this country was instrumental in establishing a preference for electrocution. Curran & Casscells, The Ethics of Medical Participation In Capital Punishment By Intravenous Drug Injection, THE NEW ENGLAND JOURNAL OF MEDICINE, 1980, J.A. at 52.

The choice of the lethal

injection method of execution differs significantly from these earlier situations, however, and raises new ethical difficulties for health professionals. First, lethal injection -- unlike guillotining and electrocution -- requires the direct and contemporaneous use of biomedical knowledge and skills (formerly used exclusively for healing) in the act of killing.

Furthermore, experience since the 18th and 19th centuries has caused a re-examination of the use of biomedical knowledge in killing, and especially of the role of physicians in such activities. Indeed, the lethal injection legislation itself has raised again the spectre of medicalized killing that has haunted the medical community in this century.

The involvement of physicians with "painless death" at the behest of the state had its most malignant flowering in Nazi Germany. In 1920 two distinguished men -- a jurist, Karl Binding, and a psychiatrist, Alfred Hoche -- published The Release of [Permission For] the Destruction of Life Unworthy of Life. That book, its thesis expanded and exploited by the Nazi hierarchy, provided a medical vocabulary for Nazi campaigns of "euthanasia" and led to extensive medical complicity in the design and operation of the death camps. Lifton, Medicalized Killing In Auschwitz, 45 PSYCHIATRY 283, 291 (1982).

Similar perverse uses of medical expertise have been documented in reports of doctors' participation in

torture carried out in recent years in Chile, Iran and Argentina. Amnesty International, Danish Medical Group, EVIDENCE OF TORTURE: STUDIES BY THE AMNESTY INTERNATIONAL DANISH MEDICAL GROUP (1977). According to Alexander Solzhenitsyn, the use of medical knowledge to enhance interrogations is a routine feature of Soviet prison camps. A. SOLZHENITSYN, GULAG ARCHIPELIGO 1918-1956, at 208, (1976).

These actions by physicians stand in stark contrast to the profession's ethical codes. For example, the Hippocratic Oath from its earliest versions has stated that:

> I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrongdoing. Neither will I

> administer a poison to anyone when asked to do so nor will I suggest such a course.

Organized medical groups have taken pains to draw the line that German physicians of the 1930's and physicians working with modern-day totalitarian regimes failed, and continue to fail to see (to the shame of their profession and of the societies of which they are or were a part). The American Medical Association, the American Nurses' Association, The American Psychiatric Association, the World Medical Association and the British Medical Association have all condemned the participation of medical personnel in executions. The American Medical Association, in a statement approved by its House of Delegates, has summed up the

view of all health professionals that: "A physician as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution." See Judicial Council of the American Medical Association, Current Opinions--1984, §206.

Since nurses, nurse practitioners, and medical technicians follow similar ethical precepts, it is unlikely that other trained personnel will be available to perform executions that physicians refuse to undertake. Moreover, allied health professionals function ordinarily only under a physician's orders. Cf., Fla. Stat. Ann., Title XXIX, §§461.00-461.023 (West 1979); Hernicz v. Florida, 390 So.2d 194 (Fla. 1st Dist. Ct. App. 980)

(nurse practitioner's license suspended after treatment without physician's specific authorization).

Nor does it seem likely that medical personnel will be willing to train non-professionals in the skills necessary for a quick, painless execution. See Affidavit of Ward Casscells, M.D., J.A. at 51. The profession believes that the perversion of medical knowledge, not the physical presence of medical personnel, is at issue.

The refusal of health care professionals to participate directly or indirectly in lethal injections is important not merely to maintain professional standards of ethics but to avoid the "breakdown, or threatened breakdown, of distinctions between healing and killing" which could have

ominous implications for society, as eminent psychiatrist and cultural historian Robert Jay Lifton has observed:

> In modern experience, the use of advanced technology radically alters whatever balance might have been maintained between healing and killing in the past. As the Nazis demonstrate, science in general and biology in particular -- however distorted or falsified -- can be mobilized on behalf of a murderous claim to healing.
> Lifton, supra at 304.

These considerations mandate that the FDA recognize that this unprecedented use of drugs approved for other purposes cannot be overlooked. Even if the moral concerns of the medical community are disregarded, the refusal of that community to participate in executing prison-

ers cannot be ignored. The absence from lethal injections of trained medical personnel raises the substantial possibility of protracted, painful deaths.

II

THE FDCA REQUIRES THE FDA TO DETERMINE WHETHER THE DRUGS AND PROCEDURES USED FOR EXECUTION ARE IMPERMISSIBLY AVAILABLE FOR THIS USE

A) The Agency Must Protect The "Consumers" -- Including Jurors And Legislators -- From Unjustified Reliance On Drugs Not Proven To Be Appropriate For Their Contemplated Use

Judge Scalia believes that the states are the "consumers" of these lethal drugs;[4] the respondents believe that the prisoners themselves will b

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4 Chaney v. Heckler, supra, 718 F.2d at 1198.

the "consumers." Whichever view is taken, the interests of both groups have been betrayed by the FDA's failure to conduct even a sketchy inquiry into safety and effectiveness. The hazards for the prisoners are obvious. The hazards to the states, their legislators and their jurors, are different, but no less important.

From the point of view of the prisoners, the record in this case promises a substantial risk of slow, painful death. From the point of view of the states and their citizens, it promises the realization that the new form of execution, chosen for its humaneness, is in fact a macabre placebo. For the Agency to fail to conduct an inquiry leaves the official "consumer" of the unreviewed drugs at

risk of perpetrating cruel and unusual punishment. The legislators involved apparently intended just the opposite; they intended the "extinguishing of life" in as painless a way as possible. They believed that they were employing tested pharmaceuticals, but these drugs have never been tested for this purpose. They believed that the drugs would be administered by experienced physicians; but no physician is experienced in killing, and -for ethical reasons- none will act as an executioner. Likewise, jurors in imposing the death penalty may take comfort in the belief that a painless method will be employed. The Agency should act to protect the prisoners, but also to protect the jurors who, having voted for a dignified, medical execution, may be

forced to read later of torturous, amateur efforts to kill brought on as a consequence of their votes.

It may be that an agency inquiry can lay to rest the questions about efficacy and safety raised by respondents. Without an inquiry, it would be irresponsible for the Agency to ignore them. Petitioners to the contrary, an Agency inquiry seems both the most reliable forum for an inquiry and the one most likely to prevent successive individual litigation of the same claim.

In effect, the Agency has been drawn into a process with fundamental constitutional overtones. As this Court has written:

> Punishments are cruel when they involve torture or

> a lingering death; but the punishment of death is not cruel within the meaning of that word as used by the Constitution. It implies there is something inhuman and barbarous, something more than the mere extinguishing of life. In re Kemmler, 136 U.S. 436, 447 (1890) .

The unrefuted evidence presented to the agency and to the courts in this matter suggests the high risk of something of this kind occurring in hundreds of lethal injection executions.

B) The FDCA Compels An Agency Investigation Of The Uses Of Previously Approved Drugs In The Novel Use Of Lethal Injection

The Respondent's administrative petition sought to inform the Secretary of numerous problematic features of the lethal injection procedures. It contained scientific evidence from a variety of sources uniformly demon-

strating that the drugs which the states plan to use for lethal injection executions are not "safe and effective" for that purpose. When the scientific materials are reviewed it is apparent that the Agency's assertion that they are "not pertinent" is not merely arbitrary, but perverse. Pet. App. 86a. The documents that the Agency dismissed without apparent interest illuminate in the clearest way the extent to which the superficial similarities between the contemplated executions and the medical use of drugs mask fundamental and disturbing differences.

No one can seriously argue that an "approved" use of drugs occurs when the drugs involved are neither tested for their new purpose nor employed as an aspect of the practice of medicine by a

trained physician. 21 U.S.C. §352(f); 37 Fed. Reg. 16503 (1972). The only evidence before the Agency, however, was that just such a situation was about to arise.

Whether there is some reason to hope that more reassuring information may come to light during the course of an FDA inquiry into the safety and effectiveness of lethal injection procedure is, of course, another question. Amici do not seek to prejudge the outcome of that investigation. They do argue, however, that the unexamined medical considerations surrounding lethal injection executions fully warrant, indeed compel, an investigation if the Agency is to fulfill its duty under the FDCA.

CONCLUSION

Amici, therefore respectfully urge that the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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This will certify that on this 29th day of September, 1984, I mailed three copies of the foregoing Brief, to the Solicitor General of the United States, Department of Justice, Washington, D.C. 20530, counsel for petitioner and to David E. Kendall, Esquire. 839 Seventeenth Street, N.W., Washington, D.C. 20006, counsel for the respondents.

I further certify that all parties required to be served have been served.

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RESPONDENT'S

BRIEF

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No. 83-1878

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, *Petitioner*,

v.

LARRY LEON CHANEY, *et al.*, *Respondents*.

On Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

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QUESTIONS PRESENTED

1. Whether a decision of the Food and Drug Administration ("FDA") not to enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") with regard to the unapproved use of drugs for lethal injection is subject to judicial review under the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

2. Whether the FDA's decision not to enforce the FDCA to ensure that the drugs used for lethal injection would effect a quick and painless death is an abnegation of the FDA's statutory duty and is arbitrary and capricious.

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1984

No. 83-1878

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL., RESPONDENTS

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS

Statutes Involved

Relevant provisions of the Administrative Procedure Act, 5 U.S.C. §§ 551 et seq., and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., not reprinted in the appendix to the government's brief (Br. for Pet.), are reprinted

in an appendix to this brief (App., infra, 1a-16a).

STATEMENT OF THE CASE

1. Introduction

This action arises out the attempt by the Food and Drug Administration ("FDA") to usurp Congressional authority by unilaterally carving an exemption out of the statute it is mandated by Congress to enforce. At issue is the extent to which there is judicial review of such executive abnegation of a Congressional mandate of enforcement responsibility. Simply put, the question is whether the executive can "arbitrarily and capriciously refuse to exercise its regulatory jurisdiction" under the guise of enforcement discretion despite a contrary legislative mandate. Pet. App. 4a. The danger posed by such unilateral agency action is magnified here by the fact that the Federal Food, Drug, and Cosmetic Act

("FDCA" or the "Act") was passed by Congress for the protection of individual consumers of drugs, including those whom the FDA has attempted to remove from the Act's coverage.

Since 1977, fifteen States[1/] have enacted statutes mandating the use of certain drugs for a radically new purpose: the execution of human beings by lethal injection. Prisons in these fifteen states currently house 452 persons[2/] under sentence of death. The eight respondents were convicted of murder and sentenced to be executed[3/] by

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1/ These lethal injection statutes are collected at footnote 1, page 2, of the Brief for Petitioner. Mississippi should be added to the Government's list. Miss. Code, § 99-19-51, Miss. Sen. Bill 2185, Reg. Sess. 1984.

2/ NAACP Legal Defense & Educational Fund, Inc., Death Row, USA, at 5-18 (Aug. 1, 1984).

3/ Since this lawsuit was filed, respondent Chaney's death sentence has been vacated by the United States Court of Appeals for the Tenth Circuit (Chaney v. Brown, No. 83-1862 (March 21, 1984) (slip op.)), and the State has petitioned for certiorari in this Court, Brown v. Chaney, No. 84-169. Respondent Franks' conviction has been reduced to second degree murder and his sentence of death vacated (Footnote Continued)

lethal injection pursuant to the Oklahoma and Texas statutes.

Lethal injection involves the use of FDA-approved drugs, by non-doctors, in a new, non-therapeutic and non-medical fashion for which their safety and effectiveness have never been tested. Notwithstanding the hopes of its advocates that the lethal injection of drugs would be a more "humane" and less painful means of executing people than the traditional methods,[4/] there is in fact substantial scientific evidence that these drugs' use under prison conditions is likely to produce agonizingly slow and painful death.

(Franks v. State, 636 P.2d 361 (Okla. Crim. App. 1981), cert. denied, 455 U.S. 1026 (1982)), and respondent Morgan's sentence of death has been vacated (Morgan v. State, No. F79487 (Okla. Ct. Crim. App.) (November 15, 1983) (slip op.)).

4/ See Christianson, Corrections Law Developments: Execution by Lethal Injection, 15 CRIM. L. BULL. 69, 70-73 (1979).

2. The Statutory Framework

The FDCA prohibits the interstate distribution of a "new drug" (including any previously approved drug that is being used for a new purpose) unless the Secretary of Health and Human Services has approved an application supported by substantial evidence of the drug's safety and effectiveness for its specified purpose. 21 U.S.C. § 355(a). The term "new drug" is defined by the FDCA, 21 U.S.C. § 321(p)(1), to mean "[a]ny drug . . . not generally recognized, among experts . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . ."

This Court has interpreted this provision to require the demonstration of an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in the Act, 21 U.S.C. §355(d). United States v. Rutherford, 442 U.S. 544,

549-550 n.7 (1979). See App. hereto at 6a-9a.

The FDCA's mandate that drugs be "safe" and "effective" has, in the case of drugs used to produce death in animals, been construed as a requirement that the drugs produce "quick" and "painless" death. In such a case, the FDA has successfully argued that the relevant criteria include: "(1) the drug's ability to cause death without pain and discomfort; (2) the time required to produce loss of consciousness; (3) the time required to produce death; (4) the reliability of the drug to obtain consistently effective results . . . ." United States v. Beuthanasia-D Regular, [1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶38,265, at 39,129 (D. Neb. 1979).

The FDCA also prohibits the misbranding of any drug in interstate commerce, 21 U.S.C. § 331(b), and any act with respect to a drug while it is "held for sale" after

shipment in interstate commerce that results in its being misbranded. 21 U.S.C. § 331(k). A drug is misbranded "[u]nless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(f). The FDA has broad enforcement powers.[5/]

The FDA has not issued approvals for the use of any drug for the lethal injection of a human being. J.A. 108, 111. The government concedes, and the district court below found, that the drugs to be used in lethal injection are manufactured for distribution and sale in interstate commerce.

5/ See, e. g., 21 U.S.C. §§ 332(a), 333, 334, 371-375.

J.A. 107; Pet. App. 65a. Therefore, lethal injection involves the untested and unapproved use of drugs manufactured, distributed and sold in interstate commerce for the non-medical purpose of killing human beings.

3. The Administrative Petition and Decision

In December 1980, respondents petitioned the Secretary of Health and Human Services, and the Secretary's agent, the FDA Commissioner, in accordance with 21 C.F.R. § 10.30 to enforce the FDCA and to take steps to regulate the unapproved use of drugs for lethal injection. J.A. 16-34. Respondents also requested an evidentiary hearing on any controlling issue of fact. J.A. 33.

Respondents' administrative petition, J.A. 16-103, contained a detailed recitation of the known evidence concerning lethal injection. The documentation submitted by

respondents established that there is strong evidence that the lethal injection of drugs is not a "safe and effective" means of executing people and that its use poses a substantial threat of torturous pain to persons being executed. Respondents submitted affidavits from leading medical and scientific experts[6/] which aver that there is by no means an "expert consensus" founded upon "substantial evidence" consisting of "adequate and well-controlled investigations" that the drugs to be used to execute people will have the effect they purport or are represented to have, to wit, that they will

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6/ Two of the affiants are accomplished anesthesiologists familiar with the drugs specified for use in lethal injection as well as the intravenous injection procedure mandated by the statutes and their interpreting regulations. Dr. Richard S. Hodes is a former president of the Florida Medical Association. J.A. 69. Dr. Leroy D. Vandam is Professor of Anesthesia, Emeritus, at Harvard Medical School, Anesthesiologist to Boston's Peter Bent Brigham Hospital, and Director of Anesthesiology at the Hospital at Parker Hill in Boston, a hospital run by the Harvard Community Health Plan. J.A. 78.

produce loss of consciousness and death quickly and without pain and discomfort. J.A. 50-51, 69-71, 78-80. There is no published scientific data or information which in any respect addresses the use of these drugs as a means of execution, much less establishes their effectiveness. Id. Nor are there any adequate and well-controlled investigations establishing the effectiveness of these drugs for a lethal injection. Id.

The injections, moreover, cannot be performed by medical personnel. The American Medical Association and professional medical societies in several states with lethal injection statutes have passed or endorsed resolutions declaring that a physician, as a member of a profession dedicated to preserving life, should not be a participant in a legally authorized execution other than to make a determination or certification of death. J.A. 49. The

licensing laws and ethical standards for nurses and medical technicians would also prevent them from carrying out a lethal injection. J.A. 51.[7/]

In July 1981, the Secretary's agent, the Commissioner of the FDA, sent counsel for respondents a letter, Pet. App. 81a-86a, summarily rejecting respondents' petition without affording them an evidentiary

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7/ The affidavits in the administrative record explain why the successful administration of a painless lethal injection and the determination of the correct dosage of drugs to be used would be very difficult even for the most highly trained and experienced of physicians. In practice, however, the risks of improper administration or determination of dosage in the context of lethal injections are substantially greater because highly trained expert physicians and other health professionals will not -- indeed, legally and ethically cannot -- participate in such activity. As explained in the affidavit of Dr. Ward Casscells, a physician who has written on the subject of medical ethics, J.A. 48, participation of a physician in an execution by lethal injection, be it through the ordering of the drugs, the preparation of the dosage, the actual administration of the injection or the supervision of others carrying out these tasks, would be in direct violation of the physicians' Hippocratic Oath, the ethical guide of the medical profession for 2,500 years. J.A. 49-50.

hearing, deeming the evidence they had submitted "not pertinent," id. at 86a, and refusing to take any of the action sought by the petition. The Commissioner conceded that "FDA as a general matter has the authority and responsibility to regulate certain drug uses not indicated in the labeling for the products." Id. at 83a. Nevertheless, the Commissioner continued, "we do not believe that such authority extends to the State-sanctioned use of lethal injection." Id. Therefore, the FDA denied respondents' petition on two distinct grounds: (1) "the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction and, therefore, . . . FDA has no authority to take the actions your petition requests," id. at 82a; and (2) if FDA had jurisdiction, "we would be authorized to decline to exercise it under our inherent discretion to

decline to pursue certain enforcement matters," id. at 85a.

4. Decisions in the Courts Below

In September 1981, respondents filed a complaint (J.A. 5-15) seeking declaratory relief and an order compelling the Secretary of Health and Human Services to take the requisite steps to enforce the FDCA with regard to the unapproved use of drugs in state-mandated lethal injections.

The district court issued an opinion and order (Pet. App. 63a-80a) granting the Secretary's motion for summary judgment on August 30, 1982. The district court held that the Commissioner's decision to refrain from interfering with the implementation of state capital punishment statutes constituted a defensible exercise of his

enforcement discretion under the FDCA. Id. at 64a.[8/]

On October 14, 1983, the court of appeals, with Judge Scalia dissenting, vacated the district court judgment and remanded "with instructions to order the agency to fulfill its statutory function." Id. at 36a. Both the majority and the dissent (id. at 9a-12a, 54a) rejected the government's primary argument below, that because state penal systems, like physicians, are licensed by the States, the unapproved use of drugs for lethal injection is exempt by analogy to the FDCA's "practice-of-medicine" exemption.[9/]

8/ The district court declined to rule upon the FDA's assertion that it does not have jurisdiction to require states to comply with the requirements of the FDCA regarding drugs used in lethal injections. Pet. App. at 73a.

9/ The court of appeals observed that the "FDA has in fact regulated drugs used in prison clinical investigations . . . and in veterinary practices . . ." and that in "both situations FDA has rejected arguments that it does not have authority to (Footnote Continued)

The court of appeals held that the use of drugs for the unapproved use of execution results in their being "misbranded" and therefore in violation of 21 U.S.C. § 331(b), which prohibits any misbranding in interstate commerce. In addition, the court of appeals held that lethal injection violates 21 U.S.C. § 331(k), which prohibits any action taken upon a drug while such drug is held for sale after shipment in interstate commerce and results in the drug being misbranded, and which section, the court of appeals observed, was expressly enacted by Congress to make the FDCA applicable at each stage of the distribution process from the manufacturer to the ultimate user of the drug, whether or not there was a "sale" in the technical legal sense. Id. at 14a-17a.

The court of appeals noted that this Court's admonishment to "construe narrowly

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regulate unapproved uses of approved drugs." Id. at 12a (citations omitted).

the 'committed to agency discretion' exception" of Section 10 of the Administrative Procedure Act ("APA"), 5 U.S.C. § 701(a)(2), and "'to find it applicable only in those rare instances where the governing statute is drawn in such broad terms that in a given case there is no law to apply,'" applies with equal force to the "review of agency enforcement . . . decisions." Id. at 21a-22a. Therefore, the court of appeals rejected the government's argument that the FDCA gives the FDA "absolute discretion" over enforcement decisions. Id. at 20a, 17a-38a (emphasis in original).

In determining whether there was "law to apply" to the FDA decision not to enforce the FDCA to ensure that drugs used for lethal injection will effect a quick and painless death, the court of appeals held that the express terms of the FDCA, a 1972 FDA policy statement (relied upon by the FDA in the Commissioner's letter to respondents,

Pet. App. 83a) and a growing body of case law interpreting the statute provided it with "more than enough law to apply" to the FDA's decision, and that therefore this decision is subject to judicial review. Id. at 25a-26a.

Based upon its "searching and careful" review of the administrative record and the agency's stated reasons for inaction, the court of appeals held that the FDA's decision was arbitrary, capricious, and without authority of law. Id. at 30a-35a. First, the court of appeals found that the Commissioner's claim that his legal authority in this area is uncertain is irrational in light of FDA's 1972 policy statement about its enforcement duties and the agency's prior assertion of jurisdiction over drugs used in State-licensed clinical investigations employing prisoners as research subjects and in state-licensed veterinary practices to kill animals. Second, in light of

the uncontroverted evidence submitted to the FDA (but deemed "not pertinent" by it, id. at 86a) that drugs used in lethal injection pose a substantial threat of torturous pain to hundreds of persons under sentence of death, the court of appeals rejected the agency's claim that these drugs do not pose a serious danger to the public health:

> [T]his claim rationally cannot stand next to FDA's earlier assertion that prisoners in clinical investigations and dogs in veterinary clinics were in "serious danger" from the unapproved use of approved drugs. If drugs used in these contexts pose a "serious threat" to the public health, then certainly drugs used to kill human beings pose such a threat.

Id. at 34a (footnote omitted).

SUMMARY OF ARGUMENT

I.

This Court has repeatedly and consistently held that a strong presumption favors judicial review of agency action, including agency enforcement action. Only a showing by "clear and convincing evidence" that Congress intended to restrict an aggrieved person's access to the courts will preclude review. Consequently, this Court and lower courts on numerous occasions have reviewed agency enforcement decisions and ordered agencies to take enforcement measures.

Judicial review of agency non-enforcement decisions is essential to ensure that unelected administrators do not thwart congressional intent by unilaterally ignoring their duties. The danger posed by such unilateral agency action is magnified where, as is the case here, Congress enacted a statute for the protection of individuals

whom an agency has attempted to remove from the act's coverage. In performing this review function, the judiciary does not make policy. To the contrary, it merely ensures that agency action is consistent with the policy announced by Congress.

The FDCA, the government concedes, does not preclude judicial review. Therefore, FDA's non-enforcement decision is subject to judical review unless it is "committed to agency discretion by law." 5 U.S.C. § 701(A)(2). This is a "very narrow exception . . . applicable in those rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply.'" Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971). The express language of the FDCA, FDA policy statements, and prior case law, either standing alone or together, provide ample "law to apply" to the FDA's

decision not to enforce the act with regard to lethal injection drugs.

1. The FDCA contains criteria by which noncompliance with the Act can be determined and sets forth measures available to enforce the Act. A state prison's use of drugs as a means of lethal injection results in these drugs being "misbranded" because the labels of the drugs do not contain either adequate directions for this unapproved use or adequate warnings that this use may be dangerous or unsafe, to wit, directions which would prevent a slow, torturous death. 21 U.S.C. § 352(f). The government agrees these drugs are misbranded. Br. for Pet. 10 n.7. The misbranding of any drug in interstate commerce is prohibited, 21 U.S.C. § 331(b), as is the misbranding of a drug while it is held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k).

2. Furthermore, in a statement published in the Federal Register in 1972,

FDA interpreted the Act to require it to take enforcement action to prevent the unapproved use of approved drugs, as in lethal injection: "[W]here the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public." 37 Fed. Reg. 16503, 16504 (1972) (emphasis added). Finally, section 306 of the Act, 21 U.S.C. § 336, requires the Secretary to report for prosecution or for the institution of libel or injunction proceedings major violations. The use of misbranded drugs for lethal injection and the substantial threat of a slow, torturous death that this case poses cannot rationally be characterized as anything but a major violation of the Act mandating the Secretary to report the

violation for the institution of enforcement proceedings.

FDA admits that it is still governed by its 1972 statement of enforcement policy. Pet. App. 83a. This clear statement of enforcement policy is sufficient by itself to provide "law to apply" to the decision here.

3. FDA's wholesale refusal to enforce the Act here also flies in the face of a growing body of court and FDA interpretations of the Act. These precedents provide sufficient criteria by which to measure compliance with the Act. FDA admits that it will frequently act to prevent the sale of approved drugs for unapproved purposes, and courts have uniformly condemned the unapproved use of approved drugs outside the practice of medicine. FDA has initiated actions to ensure that drugs used by veterinarians to kill animals will produce a quick and painless death and has issued

regulations requiring animal euthanasia drugs to be proven to produce "humane and painless death," when used as directed.

4. The government has failed to meet its heavy burden of showing by "clear and convincing evidence" that Congress intended to prohibit judicial review of FDA enforcement decisions. The express language of the Act provides for judicial review in several areas, 21 U.S.C. §§ 346(a)(i); 348(a); 355(h); 360(g); 371(f), and there is no evidence Congress meant to preclude traditional avenues of judicial relief.

Without judicial review, respondents will have no way of obtaining the protections Congress intended to provide them in the FDCA. Thus, Congress' desire to protect individual drug consumers from unsafe and ineffective drugs will be thwarted.

II.

FDA's non-enforcement decision should be set aside because it is an abnegation of its statutory duty and is arbitrary and capricious.

1. An agency's categorical refusal to exercise its jurisdiction is an act beyond its delegated power. Office Employes International Union v. Labor Board, 353 U.S. 313 (1957). FDA's wholesale disregard of state lethal injection is contrary to the intent of Congress and beyond FDA's power and must be set aside.

2. FDA's stated reasons for its non-enforcement decision plainly reveal that this decision was arbitrary and capricious. FDA has now abandoned its primary reason for non-enforcement, the unfounded claim that it had no jurisdiction over state-mandated activity. Both the court of appeals and the dissent rejected this claim. Pet. App. 9a-12a, 54a.

Having jettisoned the major basis of its decision, FDA has fallen back on its make-weight, secondary reasons. Given the unsubstantial nature of FDA's primary reason, the secondary reasons are inherently suspect. In fact, these "reasons" are nothing more than a restatement of FDA's unfounded claim that it has no jurisdiction over state-mandated activity couched in different terms.

The uncontroverted affidavits of expert anesthesiologists demonstrate that lethal injection poses a substantial risk of inflicting a slow, torturous death on hundreds of persons. Thus, FDA's claim that lethal injection is not a threat to public health is totally unfounded, particularly in light of its enforcement of the Act to ensure that drugs used to kill animals will produce a quick and painless death and to protect state prisoners in clinical investigations.

ARGUMENT

The issue presented in this case is a very narrow one. It is not whether some particular regulatory action should be taken by the FDA against lethal injection drugs. Rather, it is whether the FDA may completely abnegate its responsibilities for regulating the unapproved use of approved drugs to execute humans or whether instead it is obligated to undertake its enforcement powers responsibly and consistently with applicable law.

I. The Food and Drug Administration's Decision Not to Enforce the Federal Food, Drug, and Cosmetic Act With Regard to the Unapproved Use of Drugs for Lethal Injection Is Subject to Judicial Review Under the Administrative Procedure Act.

A. A Strong Presumption Favors Judicial Review of All Agency Action, Including Enforcement Decisions

The Administrative Procedure Act ("APA") provides that all final agency action is subject to judicial review unless

such review is precluded by statute or the action is committed by law to agency discretion. 5 U.S.C. § 701(a)(1), (2).[10/] This Court has long recognized that a strong presumption favors judicial review of agency action. With respect to the FDA, "judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." Abbott Laboratories v. Gardner, 387 U.S. 136, 140 (1967). The APA "embodies the basic presumption of judicial review to one 'suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action.'" Id. The legislative history of the APA "manifests a congressional intention that it cover a broad spectrum of administrative actions, and this Court has echoed

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10/ The APA authorizes a court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

that theme by noting that the Administrative Procedure Act's 'generous review provisions' must be given a 'hospitable' interpretation." Id. at 140-141 (footnote omitted). "'The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review,'" id. at 140 n.2, and it is "only upon a showing of 'clear and convincing evidence' of contrary legislative intent [that a court should] . . . restrict access to judicial review." Id. at 141.[11/]

This strong presumption favoring judicial review of agency action applies with equal force to agency enforcement decisions. "In the absence of an express prohibition in the [statute] the Secretary [of

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11/ Accord: Southern Railway Co. v. Seaboard Allied Milling Corp., 442 U.S. 444, 462 (1979); Dunlop v. Bachowski, 421 U.S. 560, 567 (1975); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971); Rusk v. Cort, 369 U.S. 367, 377-380 (1962).

Labor], therefore, bears the heavy burden of overcoming the strong presumption that Congress did not mean to prohibit all judicial review of his decision [not to bring a civil action against the union to set aside an allegedly invalid election]." Dunlop v. Bachowski, 421 U.S. 560, 567 (1975).[12/] In point of fact, one of the primary cases relied upon by the government for its argument that agency enforcement decisions are generally unreviewable, Southern Railway Co. v. Seaboard Allied Milling Corp., 442 U.S. 444 (1979), cites approvingly and relies upon Dunlop v. Bachowski, supra, for the proposition that judicial review of agency enforcement decisions is favored:

12/ Accord: Seafarers International Union v. United States Coast Guard, 736 F.2d 19, 29 (2d Cir. 1984) ("[t]here is a strong presumption that an agency's exercise of its enforcement discretion is reviewable."). Cf. Barlow v. Collins, 397 U.S. 159, 166 (1970) ("preclusion of judicial review of administrative action adjudicating private rights is not to be lightly inferred").

"we will not lightly interpret a statute to confer unreviewable power on an administrative agency," 442 U.S. at 454.[13/]

The government ignores the consistent, unambiguous language in these cases and asserts flatly that "administrative enforcement decisions," like "prosecutorial" ones, have traditionally been committed to "unreviewable executive discretion" and "generally are not reviewable." Br. for Pet. 16, 18. This proposition is seriously overblown even as regards prosecutorial decisions to present criminal charges, the sort of decision involved in nearly all of the cases cited by the government to support it

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13/ The Court found in Southern Railway Co. that review was precluded only by "the necessary 'clear and convincing evidence that Congress meant to prohibit all judicial review' of the Commission's limited decision not to initiate an investigation. . . .", id. at 462, and the Court again relied upon Bachowski for this requirement.

(id.).[14/] But criminal prosecution is, in

14/ Cases such as Bordenkircher v. Hayes, 434 U.S. 357 (1978), confer considerable discretion upon criminal prosecutors, but do not absolutely immunize such discretion from judicial review.

> There is no doubt that the breadth of discretion that our country's legal system vests in prosecuting attorneys carries with it the potential for both individual and institutional abuse. And broad though that discretion may be, there are undoubtedly constitutional limits upon its exercise.

Id. at 365. Thus, for example, criminal prosecutors are not free to engage at will in recriminatory prosecutions, see Blackledge v. Perry, 417 U.S. 21 (1974); United States v. Goodwin, 457 U.S. 368, 384 & n.19 (1982) (dictum), or to disregard the limitations set by plea bargains upon their power to seek otherwise lawful sanctions, e.g., Santobello v. New York, 404 U.S. 257 (1971); Blackledge v. Allison, 431 U.S. 63 (1977). See also Cooper v. United States, 594 F.2d 12 (4th Cir. 1979); United States v. Ruesga-Martinez, 534 F.2d 1367, 1369 (9th Cir. 1976); United States v. Cowan, 524 F.2d 504 (5th Cir. 1975), cert. denied, 425 U.S. 971 (1976); Nader v. Saxbe, 497 F.2d 676, 679-680 n.19 (D.C. Cir. 1974) ("the exercise of prosecutorial discretion, like the exercise of Executive discretion generally, is subject to statutory and constitutional limits enforceable through judicial review"); United States v. Ammidown, 497 F.2d 615, 622 (D.C. Cir. 1973) (court may review to determine "[w]hether. . . the action of the prosecuting attorney is such a departure from sound prosecutorial principle as to mark it an abuse of prosecutorial discretion").

any event, plainly distinguishable from administrative proceedings, where "[i]n appropriate circumstances the Court has made clear that traditions of prosecutorial discretion do not immunize from judicial scrutiny cases in which the enforcement decisions of an administrator were motivated by improper factors or were otherwise contrary to law." Marshall v. Jerrico, Inc., 446 U.S. 238, 249, 249 n.11 (1980), citing Dunlop v. Bachowski, 421 U.S. 560 (1976); Adams v. Richardson, 480 F.2d 1159 (D.C. Cir. 1973) (en banc) (per curiam); Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1971); Medical Committee for Human Rights v. SEC, 432 F.2d 659, 673 (D.C. Cir. 1970), vacated

as moot, 404 U.S. 403 (1972).[15] Criminal prosecutorial decisions are made to protect society as a whole. Private individuals have only an indirect interest in the enforcement of the criminal laws, and individual persons therefore generally have no standing to challenge the criminal prosecutor's enforcement decisions. See, e.g., Linda R.S. v. Richard D., 410 U.S. 614 (1973). Administrative enforcement decisions, on the other hand, have a direct impact on the individuals whom the statutes were enacted to protect or to benefit: "the decision to enforce -- or not to enforce -- may itself result in significant burdens on a . . . statutory beneficiary. . . ." Marshall v. Jerrico, Inc., supra, 446 U.S.

15/ See Note, Judicial Review of Administrative Inaction, 83 COLUM. L. REV. 627, 657-661 (1983), for additional discussion of why the analogy to criminal prosecutorial discretion is inappropriate for determining the reviewability of agency nonenforcement.

at 249. Consequently, this Court and lower courts[16] in numerous cases have held repeatedly that agency enforcement decisions are reviewable.

16/ See, e.g., Dunlop v. Bachowski, 421 U.S. 560 (1975) (reviewed Secretary of Labor's refusal to file suit to invalidate union election); Leedom v. Kyne, 358 U.S. 184 (1958) (ordered NLRB to set aside certification of bargaining unit as contrary to Congressional intent); Office Employes International Union v. Labor Board, 353 U.S. 313 (1957) (held that NLRB could not renounce investigatory and enforcement jurisdiction over entire category of employers); Natural Resources Defense Council v. EPA, 683 F.2d 752, 753, 767-768 (3rd Cir. 1982) (ordered regulation whose effective date had been delayed be put into effect); WWHT, Inc. v. FCC, 656 F.2d 807 (D.C. Cir. 1981) (reviewed FCC denial of petition to institute rulemaking proceedings); Carpet, Linoleum & Resilient Tile Layers, Local Union No. 419 v. Brown, 656 F.2d 564 (10th Cir. 1981) (held that federal officials may be required to enforce Davis-Bacon Act); Natural Resources Defense Council, Inc. v. SEC, 606 F.2d 1031 (D.C. Cir. 1979) (reviewed SEC refusal to promulgate rules requiring disclosure of environmental and equal opportunity information); Caswell v. Califano, 583 F.2d 9 (1st Cir. 1978) (ordered HEW to reduce time period for scheduling hearing); British Airways Board v. Port Authority of New York, 564 F.2d 1002, 1012-1013 (2d Cir. 1977) (ordered a ruling on acceptable noise levels at airports by striking down temporary rule and requiring any permanent rule be promulgated in acceptable time period); White v. Matthews, 559 F.2d 852 (2nd Cir. 1977), cert. denied, 435 U.S. 908 (1978) (ordered Secretary of HEW to cease delays in processing claims);
(Footnote Continued)

In Dunlop v. Bachowski, 421 U.S. 560

Pennsylvania v. National Ass'n of Flood Insurers, 520 F.2d 11 (3rd Cir. 1975) (ordered HUD to evaluate the necessity of disseminating flood insurance information); REA Express, Inc. v. CAB, 507 F.2d 42 (2nd Cir. 1974) (reviewed CAB decision not to prohibit use of allegedly confusing trade name); Davis v. Romney, 490 F.2d 1360 (3rd Cir. 1974) (required FHA to make reasonable efforts to determine whether homes with insured mortgages meet municipal housing code standards); Adams v. Richardson, 480 F.2d 1159 (D.C. Cir. 1973) (en banc) (per curiam) (ordered HEW to initiate enforcement actions against certain school districts); International Harvester Co. v. Ruckelshaus, 478 F.2d 615 (D.C. Cir. 1973) (remanded EPA denial of application for one-year suspension of auto emission standard as contrary to congressional intent); Rockbridge v. Lincoln, 449 F.2d 567 (9th Cir. 1971) (ordered Secretary of Interior to adopt rules governing traders doing business on Indian reservations); Environmental Defense Fund, Inc. v. Ruckelshaus, 439 F.2d 581, 584 (D.C. Cir. 1971) (required Secretary of Agriculture to commence proceedings to cancel registration of DDT by issuing cancellation notices); Environmental Defense Fund, Inc. v. Hardin, 428 F.2d 1093 (D.C. Cir. 1970) (ordered Secretary of Agriculture to rule on use of DDT); Medical Committee for Human Rights v. SEC, 432 F.2d 659 (D.C. Cir. 1970), vacated as moot, 404 U.S. 403 (1972) (reviewed agency refusal to prosecute alleged proxy violation); Trailways of New England, Inc. v. CAB, 412 F.2d 926 (1st Cir. 1969) (reviewed agency refusal to investigate airlines' allegedly discriminatory fares); International Union, United Auto. Aero. & Agric. Implement Workers v. NLRB, 427 F.2d 1330 (6th Cir. 1970) (held that NLRB could not abstain from deciding whether conduct alleged in complaint constituted unfair labor practices); Public Citizen Health Research Group v. Auchter, 554 F. Supp. 242 (D.D.C. 1983), rev'd in part, 702 F.2d
(Footnote Continued)

(1975), an unsuccessful candidate for union office asked the Secretary of Labor to investigate his claims of election fraud and to bring a civil action to set aside the election if warranted pursuant to the Labor-Management Reporting and Disclosure Act (LMRDA), 29 U.S.C. § 482. When the Secretary refused to take action on the

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1150 (D.C. Cir. 1983) (ordered OSHA to promulgate emergency standards on worker exposure to carcinogen ethylene oxide); Sierra Club v. Gorsuch, 551 F. Supp. 785 (N.D. Cal. 1982) (ordered EPA to issue proposed emission standards); Hoffman - LaRoche, Inc. v. Weinberger, 425 F. Supp. 890 (D.D.C. 1976) (permanently enjoined Secretary of HEW from implementing policy which permitted introduction of "new drugs" into interstate commerce prior to approval of requisite new drug applications); Guerrero v. Garza, 418 F. Supp. 182 (W.D. Wisc. 1976) (held that Department of Labor may be required to monitor activities of farm labor contractors employing migrant workers); Souder v. Brennan, 367 F. Supp. 808, 811 (D.D.C. 1973) (ordered Labor Department to enforce wage and hour provisions of statute); City-Wide Coalition Against Childhood Lead Paint Poisoning v. Philadelphia Housing Auth., 356 F. Supp. 123 (E.D. Pa. 1973) (required FHA to ensure that federally funded housing meets local code requirements); American Public Health Ass'n v. Veneman, 349 F. Supp. 1311 (D.D.C. 1972) (ordered Secretary of HEW to release reports reviewing efficacy of drugs and to complete evaluation of drugs).

complaint, the defeated candidate sought judicial review of the Secretary's decision not to enforce the statute. The Secretary argued that his action was unreviewable under both the precluded-by-statute and committed-to-agency-discretion exceptions of the APA, 5 U.S.C. § 701(a)(1), (2). The Court held that neither exception applied, and that the Secretary's decision to refrain from exercising enforcement power was reviewable.

The government's attempt to overrule Bachowski by characterizing the Court's holding as a "summary treatment of the issue" that "did not even discuss Section 701(a)(2) of the APA" and "did not discuss the Secretary's contention that the decision was an unreviewable exercise of prosecutorial discretion" is flatly wrong. Br. for Pet. 23, 24, 25. In point of fact, the Court expressly stated that the "Secretary's decision is not excepted from judicial

review by 5 U.S.C. § 701(a)," 421 U.S. at 566; that the statute "contains no provision that explicitly prohibits judicial review of the decision of the Secretary not to bring a civil action against the Union to set aside an allegedly invalid election," id.; and that "the statutory scheme, its objectives, its legislative history, the nature of the administrative action involved, and the conditions spelled out with respect thereto . . . [have been examined by the Court and they] do not reveal to us any congressional purpose to prohibit judicial review." Id. at 567. This reasoning is equally applicable in this case. Moreover, in rejecting the Secretary's claim that his nonenforcement decision was an unreviewable exercise of discretion, the Bachowski Court expressly adopted the detailed reasoning of the lower court: "[w]e agree with the court of appeals, for the reasons stated in its opinion, . . . that there is no merit in the

Secretary's contention that his decision is an unreviewable exercise of prosecutorial discretion." Id. at 567 n.7.[17/]

17/ The court of appeals in the Bachowski case had flatly stated that "[n]ot every refusal by a Government official to take action to enforce a statute . . . is unreviewable." Bachowski v. Brennan, 502 F.2d 79, 87 (3rd Cir. 1974). The court found the Secretary of Labor's decision reviewable for two reasons.

First, the court of appeals in Bachowski held that judicial review was proper because the Secretary's conduct could be measured against appropriate legal standards. 502 F.2d at 88. According to the court, the Secretary's decision whether to file a complaint depended solely on a straightforward factual determination whether there had been a violation of LMRDA and whether there was probable cause to believe that the violation had affected the outcome of the election. Id.

Second, "the doctrine of prosecutorial discretion should be limited to those civil cases which, like criminal prosecutions, involve the vindication of societal or governmental interest, rather than the protection of individual rights." 502 F.2d at 87. The court concluded that the legislative history of LMRDA demonstrated that Congress was concerned with the interest of individual union members in union elections, and that the action requested of the Secretary was for the benefit of individual union members, as well as for the public at large. Id.

The LMRDA's protection of individuals provided the basis on which the court of appeals in Bachowski distinguished two of the cases relied upon by the (Footnote Continued)

The many cases holding agency enforcement decisions subject to judicial review, see note 16 supra, belie the FDA's assertion of absolute discretion here. In Adams v. Richardson, 480 F.2d 1159 (D.C. Cir. 1973) (en banc) (per curiam), for example, plaintiffs sought declaratory and injunctive relief against the Secretary of Health, Education and Welfare, who they claimed had failed to enforce Title VI of

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government there -- and relied on again by the government now -- to support its arguments against judicial review. Confiscation Cases, 74 U.S. (7 Wall.) 454 (1869), and Vaca v. Sipes, 386 U.S. 171 (1967). The court of appeals noted that in both of these cases, unlike Bachowski, the enforcement actions were solely for the benefit of the public at large, as opposed to aggrieved individuals. 502 F.2d at 87-88. The Confiscation Cases were suits to confiscate property used in aid of rebellion, and thus were "for the benefit of the United States. . . ." 74 U.S. at 457. In Vaca v. Sipes, 386 U.S. 171 (1967), the Court's statement concerning the discretion of the NLRB general counsel to file unfair labor practice complaints was pure dictum, and the Court noted that "[t]he public interest in effectuating the policies of the federal labor laws, not the wrong done the individual employee, is always the Board's principal concern in fashioning unfair labor practice remedies." Id. at 183 n.8

the Civil Rights Act of 1964 by not taking appropriate action to end segregation in schools receiving federal funds. The district court found for plaintiffs and ordered the Secretary to commence enforcement proceedings against secondary and primary school districts found in non-compliance with Title VI and to take several other enforcement measures. The court of appeals, sitting en banc, affirmed the lower court's injunction with only a slight modification concerning higher education. The Secretary had argued that the enforcement of Title VI was committed to his absolute discretion and therefore was not subject to judicial review. After noting that the APA "committed to agency discretion" exception is narrow and rarely found, the court expressly rejected the applicability of cases where courts had:

> declined to disturb the exercise of prosecutorial discretion by the

> Attorney General or by United States Attorneys . . . . Those cases do not support a claim to absolute discretion and are, in any event, distinguishable from the case at bar.

Id. at 1162 (emphasis in original). "More significantly," the court of appeals found, the Secretary's enforcement policy was subject to judicial review because plaintiffs had alleged that "HEW has consciously and expressly adopted a general policy which is in effect an abdication of its statutory duty. We are asked to interpret the statute and determine whether HEW has correctly construed its enforcement obligations." Id. Judicial review of this sort--the precise kind involved in the present case--has been a staple of federal administrative law since Office Employes International Union v. Labor Board, 353 U.S. 313 (1957), and Hotel

Employees v. Leedom, 358 U.S. 99 (1958) (per curiam).[18] See note 16 supra.

These cases reflect an awareness by the courts that administrative agencies, which increasingly play a significant role in every aspect of our lives, do not always exercise their broad rulemaking and enforcement powers in conformity with the responsibilities delegated to them by Congress. Without judicial review to ensure agency fidelity to congressional mandates, the goals of Congress can be frustrated by agency inaction, whether such inaction takes

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18/ Indeed, some of the cases relied upon by the government in support of its argument that agency enforcement discretion is absolute are directly contrary to that contention. See Southern Railway Co. v. Seaboard Allied Milling Corp., 442 U.S. 444, 462 (1979), quoted at note 13 supra. Likewise, the Court in Moog Industries, Inc. v. Federal Trade Commission, 355 U.S. 411, 419 (1958), stated that the commission's "discretionary determination" as to whether an order against one company to cease and desist from illegal price discrimination should be held in abeyance until the commission proceeded against the firm's competitors was subject to judicial review and could be overturned for the "patent abuse of discretion."

the form of failure to enforce compliance with the statute and its regulations, failure to promulgate regulations, or failure to conduct hearings or investigations.

Despite the government's argument that judicial review of agency enforcement discretion is inappropriate because of the "separation of powers" doctrine, Br. for Pet. 13, "it is clear that no violence to the principle of the separation of powers arises from judicial efforts to enforce a congressional mandate." Caswell v. Califano, 583 F.2d 9, 16 (1st Cir. 1978); Nader v. Saxbe, 497 F.2d 676, 679 n.19 (D.C. Cir. 1974). When the judicial branch reviews agency action or inaction for consistency with the agency's statutory mandate, it is not usurping administrative policy-making functions. Separation of powers notions themselves mandate that the federal courts assume "responsibity for

ensuring that government officials do not negate or frustrate congressional enactments through bureaucratic arbitrariness." Pet. App. 36a.[19/]

The government argues that enforcement decisions "characteristically involve complicated questions of administration that are ill-suited for review by the Courts." Br. for Pet. 17. But, as demonstrated by the multitude of cases in which courts have reviewed enforcement discretion, see note 16 supra, this is simply not true. Quite often, agency enforcement decisions present questions of law, not administration, that require statutory construction and the definition of the agency's task under its mandate from Congress. That is plainly the case here, where the FDA's decision did not advert to a single consideration within the

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19/ See Note, Judicial Control of Systemic Inadequacies in Federal Administrative Enforcement, 88 YALE L. J. 407, 411 n.18 (1978).

realm of administrative expertise, but was based entirely upon interpretation of the FDCA and upon the FDA's unwillingness to intrude into what it conceived as an area of state penal policy. In situations which do involve mere "questions of administration," Br. for Pet. 17, dependent upon agency expertise, the government's concern is fully met by the established principle followed by the court below, that judicial review is bounded by the existence of "law to apply," Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971).

In short, the government's claim that administrative enforcement discretion is absolute is itself anathema to the separation of powers doctrine. It disregards the overwhelming weight of authority and flouts the Administrative Procedure Act. Under the APA, judicial review is unavailable only where precluded by statute, 5 U.S.C. § 701(a)(1), or where agency action is

committed by law to agency discretion, 5 U.S.C. § 701(a)(2).

B. The Express Language of the Statute, FDA Policy Statements, and Prior Case Law Provide Ample "Law to Apply" To the FDA's Decision Not to Enforce the Act With Regard To the Unapproved Use of Drugs for Lethal Injection

The court of appeals observed that "[n]either FDA nor the District Court claims that FDCA precludes judicial review," Pet. App. 20a (footnote omitted), and the Government does not contend otherwise. It argues instead that "the structure and legislative history of the FDCA reinforce the conclusion" that Congress intended the FDA to have unreviewable enforcement discretion. Br. for Pet. 13. However, this Court has repeatedly held that the § 701(a)(2) exemption ("agency action committed to agency discretion by law") is a "very narrow exception . . . applicable in those rare instances where 'statutes are drawn in such

broad terms that in a given case there is no law to apply.'" Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 410 (1971) (quoting S. Rep. No. 752, 79th Cong. 1st Sess. 26 (1945)).[20/] The express language of the FDCA itself, FDA policy statements, and prior case law provide ample "law to apply" in this case and indicate that the FDA's decision here is not one committed entirely to agency discretion.

1. The FDCA Provides "Law to Apply" To FDA's Non-Enforcement Decision

The FDCA itself contains criteria by which noncompliance with the Act can be determined and sets forth the measures available to enforce the Act, therefore providing "law to apply" to the FDA's non-enforcement decision. Bachowski v. Brennan, supra, 583 F.2d at 88; Adams v. Richardson,

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20/ Accord: Dunlop v. Bachowski, supra, 421 U.S. at 567 n.7; Abbott Laboratories v. Gardner, supra, 387 U.S. at 140-141.

supra, 480 F.2d 1159, 1162 (D.C. Cir. 1973) (en banc) (per curiam).

The Act expressly provides that a drug "shall be deemed to be misbranded" unless its label bears "(1) adequate directions for use; and (2) such adequate warnings against use . . . where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users." 21 U.S.C. § 352(f) (emphasis added). A state prison's use of drugs as a means of lethal injection results in these drugs being "misbranded" because the labels of the drugs do not contain either adequate directions for this unapproved use or adequate warnings that this use may be dangerous or unsafe --

directions or warnings which would prevent a slow, torturous death.[21/]

The Act, unambiguously provides that the misbranding of any drug in interstate commerce is prohibited. 21 U.S.C. § 331(b). Likewise, section 331(k) prohibits the doing of any act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded. 21 U.S.C. § 331(k). Not only does section 333(a) provide that any person "who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both" (emphasis added); section § 334(a)(1) further provides that any drug that is "misbranded when introduced into or while in interstate commerce or while held

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21/ The government apparently concedes, as it must, that lethal injection drugs are misbranded under the FDCA. Br. for Pet. 10 n.7.

for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce or at any time thereafter. . . ." 21 U.S.C. § 334(a)(1) (emphasis added). The drugs to be used in lethal injection are manufactured for distribution and sale in interstate commerce. J.A. 107; Pet. App. 65a. For the reasons set forth in Part II.B.1., infra, these FDCA prohibitions apply to a state prison's use of drugs for lethal injection.

Section 355(a) of the Act in similar mandatory terms[22/] provides that "[n]o

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22/ It is ultimately Congressional intent and not whether statutory language is mandatory or permissive in form which determines whether agency action is subject to judicial review. Barlow v. Collins, 387 U.S. 159, 166 (1970); Hindros v. United States Civil Service Commission, 720 F.2d 278, 293 (3rd Cir. 1983); Local 12, AFGE v. Donovan, 683 F.2d 511, (Footnote Continued)

person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug." 21 U.S.C. § 355(a) (emphasis added). The government admitted in its Answer and discovery responses that no new drug applications have been approved for any drugs to be used in lethal injections. J.A. 108, 111.

In addition, section 336 explicitly limits the Secretary's discretion to abjure enforcement action against violations of the Act. 21 U.S.C. § 336. Section 336 provides:

> Nothing in this chapter shall be construed as requiring the Secretary

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516 n.16 (D.C. Cir. 1983) ("As a general matter, permissive statutory language only affects the scope of an agency's discretion; it does not constitute a license to undertake actions that are 'arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law'").

> to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(Emphasis added.)

Congress' use of the word "minor" to limit the term "violations" manifests a congressional intent that the Secretary report all major violations for enforcement action.[23/] If Congress had intended to relieve the Secretary of her statutory obligation to report major as well as minor

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23/ See Andrus v. Glover Construction Co., 446 U.S. 608, 616-617 (1980) ("[w]here Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent"); Midland Telecasting Co. v. Midessa Television Co., 617 F.2d 1141, 1145 n.7 (5th Cir. 1980), cert. denied, 449 U.S. 954 (1981) ("[t]he existence of an explicit exemption covering certain acts is evidence that Congress did not intend to grant immunity to other acts not covered by the explicit exemptions").

violations, it would obviously not have written the word "minor" into section 336. Nor would it have written section 336 at all if it had conceived the Secretary as possessing the wholesale power of non-enforcement which the government now claims on her behalf -- a power to take no enforcement action whatsoever in any case, major or minor. The unmistakable language of section 336 confers upon the Secretary a discretion confined to minor violations, and even there confined to a choice among enforcement methods, not including an option of non-enforcement.

This interpretation of section 336 is consistent with the legislative history of the Act. Recognizing that large numbers of purely technical violations might occur, Congress drafted section 336 to relieve the Secretary of her otherwise mandatory duty to report all violations for prosecution or for libel or injunction proceedings by allowing

the Secretary to send notices and warnings to minor violators. Congress reasonably hoped that the overwhelming majority of such violators would cease their unlawful conduct upon receiving such notice.[24/] However, Congress plainly intended that major violations of the Act be prevented through strict enforcement.[25/]

2. A 1972 FDA Statement of Enforcement Policy Acknowledges FDA's Statutory Enforcement Obligations and Also Provides "Law to Apply" To FDA's Non-Enforcement Decision

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24/ "Violations of the law sometimes occur which are of technical or formal nature only . . . . Usually such violations are inadvertent and their correction can be promptly effectuated by calling them to the attention of the manufacturer. This section would authorize the enforcing agency to follow this course." S. Rep. 361, 74th Cong., 1st Sess. (1935) (referring to a nearly identical provision in a predecessor bill), quoted in C.W. DUNN, FEDERAL FOOD, DRUG, AND COSMETICS ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 263 (1938).

25/ "It is not intended that this procedure [notification of the manufacturer] would apply where the violation is more than merely technical and becomes one of substance rather than form." Id., DUNN, supra, note 24.

In 1972, as part of a proposed rulemaking, FDA published in the Federal Register a preamble which explicitly acknowledged its interpretation of its statutory duties:

> Where the unapproved use of an approved new drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public. Several alternative courses of action are available to the Food and Drug Administration under these circumstances, depending upon the specific facts of each case. These actions include: [r]equiring a change in the labeling to warn against or to approve the unapproved use, seeking substantial evidence to substantiate the use, restricting the channel of distribution, and even withdrawing approval of the drug and removing it from the market in extreme cases. When necessary, the Food and Drug Administration

> will not hesitate to take whatever action of this nature may be required to bring possible harmful use of an approved drug under control.

37 Fed. Reg. 16,503, 16,504 (1972) (emphasis added).

In the Commissioner's letter rejecting respondents' requests for enforcement action, the FDA described this preamble as "[t]he agency position on the legal status of approved labeling for prescription drugs." Pet. App. 83a. The Secretary admitted below that the FDA still abides by its 1972 statement: "The response cited a Federal Register notice of April 15, 1972 (37 Fed. Reg. 16,503), that sets forth the agency's current position o[n] the legal status of approved labeling for prescription drugs."[26/]

26/ Memorandum in Support of Defendant's Motion to Dismiss or, in the Alternative, for Summary Judgment, at 4 n.10.

This clear statement of FDA enforcement obligations as to the unapproved use of approved drugs, admittedly still in effect, also provides the requisite "law to apply" for a court to determine whether the Secretary's enforcement decision here was arbitrary, capricious, or an abuse of discretion.

The government argues that the terms "widespread," "endanger the public" and "whatever action is warranted," Br. for Pet. 30, are too "flexible" for a court to apply to FDA conduct. But these terms are no different from other terms which courts routinely interpret, and there is nothing about them that would preclude their judicial interpretation and application in a case such as this where the FDA has totally

abnegated its enforcement responsibilities.[27/]

This Court in Overton Park rejected the government's claim that judicial review was inappropriate because it would require "a wide-ranging balance of competing interests." 401 U.S. at 411. Likewise, the Court should reject the government's attempt to resurrect that argument here. The government's claim that judicial review

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27/ The terms are certainly no more "flexible" than the terms this Court considered sufficient "law to apply" in the seminal case of Citizens to Preserve Overton Park, Inc. v. Volpe, supra, 401 U.S. at 411. In Overton Park, the Court reviewed and applied § 4(f) of the Department of Transportation Act and § 138 of the Federal Aid to Highways Act. Those statutes provided that the Secretary of DOT shall not approve any program that requires using public parkland "unless (1) there is no feasible and prudent alternative to the use of such land, and (2) such program includes all possible planning to minimize harm to such park * * *." 23 U.S.C. § 138; 49 U.S.C. § 1653(f) (emphasis added). No rational distinction can be drawn between the term "all possible planning" in Overton Park and "whatever action is warranted" as used in this case. Likewise, "widespread" and "endangers the public health" are, if anything, more easily reviewed and applied than "feasible" and "prudent."

would require "surveying the potential dangers posed by all the foods and drugs marketed in this country and all the resources at the FDA's command" Br. for Pet. at 30, is apocalyptic nonsense. As the Court stated in Overton Park, "no such wide-ranging endeavor was intended." Id. Obviously FDA need not survey all drugs to determine whether the unapproved use of the specific drugs named in respondents' administrative petition poses a danger or to assess what is necessary to remove that danger.

The government also argues that its enforcement policy, although admittedly still in effect, is not "law to apply" because it is set forth in a preamble and the FDA considers such a statement to be a non-binding "advisory opinion" under its regulations. Br. for Pet. 31-32, citing 21 C.F.R. § 10.85(d). The government's argument is beside the point. Whether "binding"

or "non-binding," the preamble authoritatively recognizes and delineates FDA's duties under the FDCA, and therefore provides "law to apply" to the FDA's action here. See Southeastern Minerals, Inc. v. Harris, 622 F.2d 758, 766 (5th Cir. 1980) (FDA statement of policy "represents FDA's formal position on the use of gentian violet and obligates the agency to act in a manner consistent with that policy until it is amended or revoked"). In any event, FDA's rules expressly provide that such an advisory opinion "represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section obligates the agency to follow it until it is amended or revoked." 21 C.F.R. § 10.85(e) (emphasis added). Accord: United States v. Ewig Bros., Inc., 502 F.2d 715, 725 n.34 (7th Cir. 1974) (Stevens, J.) ("the Enforcement Guideline is binding upon F.D.A., notwithstanding the informal manner

of its release [by means of a press release], as if it were a general rule published in accord with the requirements of the Administrative Procedure Act").

The government tries to circumvent § 10.85(e) by relying on § 10.85(j), which provides that an "advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement." The government contends that the "not as a legal requirement" language of § 10.85(j) relieves it of the obligation imposed by § 10.85(e) to comply with its enforcement policy statement. Once again, the government's argument is both beside the point and wrong. Whether or not it is a "legal requirement," the statement of enforcement policy in the preamble is an authoritative statement of FDA duties, and therefore provides "law to apply" for a reviewing court. Indeed, by its own terms,

§ 10.85(j) provides that the policy statement "may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards. . . ."

In any event, the government is flatly wrong when it argues that § 10.85(j) relieves FDA of the obligations imposed by § 10.85(e). It makes no sense to say, as the government does, that FDA is "obligate[d]" to follow its advisory opinions because of § 10.85(e) but that it is not obligated because of § 10.85(j). Such a nonsensical interpretation and application of § 10.85(j) would render § 10.85(e) meaningless, and therefore could not have been intended by its drafters. Cf. Colautti v. Franklin, 439 U.S. 379, 392 (1979).

Sections 10.85(e) and 10.85(j) can be read harmoniously so that they both have meaning and are consistent with their underlying goals only if the "not as a legal requirement" language of § 10.85(j) is

limited to advisory opinions or parts thereof which impose requirements on third persons, rather than on FDA. Such an application of these two sections comports with the goals which the FDA hoped to achieve through their promulgation.[28/]

Finally, the government tries to escape the impact of the FDA's self-declared enforcement policy defining its obligations under the Act by arguing that at best the preamble is an interpretative, as opposed to legislative, rule under the APA, and as such

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28/ As the government readily admits, "[a]dvisory opinions are usually requested by persons who may be affected by FDA action." Br. for Pet. 31-32. Therefore, "[a]dvisory opinions bind the agency in the sense that the agency is usually precluded from taking action against a person or firm that has relied on such an opinion." Id. at 32. Since the formal rulemaking procedures of the FDA are not followed when an advisory opinion is issued, it would be grossly unfair to impose such an opinion upon third parties as a "legal requirement," although it would not be unfair to use it to illustrate acceptable procedures and standards. Conversely, there is no unfairness in requiring FDA to comply with its own advisory opinions. See Southeastern Minerals, Inc. v. Harris, 622 F.2d 758, 766 (5th Cir. 1980).

does not bind FDA action. However, whether the FDA's statement of its enforcement policy and obligations is characterized as a legislative or interpretative rule is irrelevant to the determination whether the statement provides "law to apply."[29/]

3. Prior FDA and Court Interpretations of the Act Provide "Law to Apply" to the FDA'S Non-Enforcement Decison

In addition to the language of the Act itself and FDA's own authoritative interpretation, case law and an FDA Compliance

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29/ Legislative rules "'have the force and effect of law,'" Batterton v. Francis, 432 U.S. 416, 425 n.9 (1977), but even if this policy statement were an interpretative rule, it would still be an authoritative pronouncement by the FDA of its obligations to enforce the Act with regard to the unapproved use of approved drugs. In the words of Justice Jackson describing the effect of interpretative bulletins of the Wage and Hour Administration, "[we] consider that the rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the Courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944).

Policy Guide provide "law to apply" to the FDA's enforcement decision with regard to unapproved use of approved drugs for lethal injection.

There are no cases which condone the unapproved use of approved drugs for a purpose such as lethal injection. To the contrary, the courts have uniformly condemned the unapproved use of approved drugs outside the practice of medicine, and this body of precedent serves as a yardstick for judicial assessment of the FDA's abdication in this case. In United States v. An Article of Drug * * * Diso-Tate, Etc., H. Ray Evers, and Meadowbrook Hospital, [1976-1977 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,086 (E.D. La. 1976), for example, the court held that the use of a drug for an unapproved purpose by a physician not licensed to practice in Louisiana constituted misbranding by the physician within the meaning of 21 U.S.C.

§ 352(f)(1). Therefore, the court issued an order enjoining the administration of the drug, holding that "injunctive relief as requested by the Government is not only lawful but also compelled." ¶ 38,086 at 38,288. Similarly, the court in United States v. Hoxsey Cancer Clinic, 198 F.2d 273 (5th Cir. 1952), cert. denied, 346 U.S. 897 (1953), ordered that an injunction be issued prohibiting the defendant, a lay person, from introducing into interstate commerce misbranded drugs which the defendant represented as a cure for cancer.

The district court in United States v. Evers, 453 F.Supp. 1141 (M.D. Ala. 1978), aff'd, 643 F.2d 1043 (5th Cir. 1981),[30/]

30/ Evers is consistent with the decisions in DisoTate and Hoxsey. In Evers, a physician, in the state in which he was licensed to practice, used drugs in his treatment of patients in a manner for which they had not been approved. The district court held that the drugs at issue were not misbranded since the physician using them was doing so as a part of the practice of medicine. 453 F.Supp. at 1149. The Fifth Circuit affirmed the (Footnote Continued)

endorsed the FDA's 1972 statement of enforcement policy, noting that "the Food and Drug Administration does have duties when it appears that the unapproved use of an approved drug becomes widespread or endangers the public's health." 453 F. Supp. at 1148. The court ruled that the FDA had the responsibility to remove misbranded drugs from interstate commerce and to prevent the use of misbranded drugs after their shipment in interstate commerce.

The case law speaks specifically to the issue of appropriate FDA enforcement action with regard to drugs used to produce death. In a case initiated by the FDA, a

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trial court's holding that a misbranding had not occurred on the separate ground that the defendant physician complied with § 352(f)(1)'s requirement of "adequate directions for use" since he was administering the drug to his own patients. 643 F.2d at 1044. Thus, the fact that Dr. Evers was a practicing physician was crucial to the holding of both courts that the FDCA had not been violated. Both the court of appeals and dissent below rejected the government's attempt to analogize lethal injection to the "practice of medicine." Pet App. 9a-12a, 54a.

federal court in Nebraska in 1979 ruled that substances used by veterinarians to kill domestic animals were "drugs" under the Act, with the result that their introduction into interstate commerce violated the Act since a "new drug" application had not been filed demonstrating that those drugs satisfy the Act's requirements of safety and effectiveness. United States v. Beuthanasia-D Regular, [1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb. 1979). The court in Beuthanasia-D Regular noted that relevant criteria in assessing the "safety" and "effectiveness" of such death-producing drugs include (1) the drug's ability to cause death without pain and discomfort; (2) the time required to produce loss of consciousness; (3) the time required to produce death; (4) the reliability of the

drug to obtain consistently effective results. Id. at 39,129.[31/]

The FDA itself applies the Act to drugs used in state prisons where the drugs are administered to state prisoners for the purpose of experimentation. In 1978, the FDA concluded that it had authority under the FDCA to promulgate regulations protecting the interests of prisoners used as research subjects in clinical investigations submitted to the FDA and promulgated proposed regulations. 43 Fed. Reg. 19,417 (1978). During the notice and comment period, some comments challenged the FDA's authority to issue these regulations on the ground that they interfered with a state's authority to regulate its penal system. Yet

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31/ This ruling is consistent with FDA Compliance Policy Guide No. 7125.17, issued on October 1, 1980, in which the FDA declared that animal euthanasia products must be formally approved by FDA after filing of a "new drug" application. "The data must establish that the product results in a humane and painless death when used as directed."

the FDA expressly rejected this argument (which it has nevertheless advanced in this case) in the context of drug investigations with state prisoners:

> One comment stated that the proposed regulations are an impermissible intrusion upon the rights of the States to manage their own prison systems. Two comments contended that FDA's regulations would violate a California law that permits prisoner research. FDA disagrees with these comments. These regulations impose no obligations on State prison authorities. They state that except in limited circumstances, the agency will not permit the use of prisoners in the clinical investigations it regulates under sections 505(i), 507(d), and 520(g) of the act or accept clinical investigations that involved prisoner subjects in support of applications for research or marketing permits for products regulated by FDA.

45 Fed. Reg. 36,388 (1980).

The case law, FDA's Compliance Policy Guide and FDA's regulation of drugs used in clinical investigations with state prisoners thus provide a third source of "law to apply" to the FDA's enforcement decision here.

C. There Is No "Clear and Convincing Evidence" That Congress Intended to Prohibit Judicial Review of FDA Enforcement Decisions

The government has failed to meet its heavy burden of showing by "clear and convincing evidence" that Congress intended to prohibit judicial review of FDA enforcement decisions. Dunlop v. Bachowski, supra, 421 U.S. at 567; Abbott Laboratories v. Gardner, supra, 387 U.S. at 141. The issue is framed "in terms of 'prohibition' rather than 'authorization' because . . . judicial review of a final agency action will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." Abbott Laboratories v. Gardner,

supra, 387 U.S. at 140. In point of fact, the express terms of the FDCA [32] and its legislative history[33] overwhelmingly demonstrate that Congress did not intend to limit judicial review.

32/ The express language of the FDCA provides for judicial review of FDA enforcement in several different areas, as the court of appeals recognized. Pet. App. 20a n.24. It is well established, by a case involving the FDCA itself, that the fact that the statute does not expressly provide for judicial review of FDA decisions regarding enforcement of the misbranding provisions of the statute is no reason to conclude that Congress intended to preclude review of such agency action. Abbott Laboratories v. Gardner, supra, 387 U.S. at 142. "Each statute in question must be examined individually . . . . Mere failure to provide for judicial intervention is not conclusive." Heikkila v. Barber, 345 U.S. 229, 233 (1953).

33/ The brief snatches of legislative history cited by the government are not to the contrary. These unrevealing excerpts merely refer to the agency's limited "discretion" under 21 U.S.C. § 336. However, there is nothing in these excerpts to support the government's argument that Congress intended such discretion to be totally shielded from judicial review. "[B]ecause the APA authorizes courts to set aside agency action that constitutes an abuse of discretion . . . . the existence of agency discretion, in itself, hardly constitutes grounds for concluding that agency action is unreviewable." Local 1219, AFGE v. Donovan, 683 F.2d 511, 515 (D.C. Cir. 1982).

In the absence of statutory language or legislative history to support its argument that Congress intended to preclude judicial review, the government falls back on a traditional in terrorem argument: "Court review of the FDA's enforcement decision would seriously impair the agency's ability to carry out its congressionally assigned role."[34] Br. for Pet. 37. According to the government, judicial review "would pressure agencies to respond to requests for enforcement action with carefully phrased and factually detailed written decisions.

34/ Ironically, only one page earlier in its brief, the government harshly criticizes the court of appeals for its mere suggestion that a "pragmatic consideration[]" like "whether judicial review will unnecessarily impede the agency in effectively carrying out its congressionally assigned role," Pet. App. 24a, is relevant to determining whether there is "law to apply." Br. for Pet. 36. However, in light of the straightforward criteria applicable to the FDA's decision, as set forth in the statute itself, the 1972 policy statement, and prior FDA and court interpretations of the statute, the court of appeals found that it "need not delve into a detailed analysis" of any such "pragmatic considerations." Pet. App. 24a.

Agencies would be forced by the threat of burdensome court proceedings and possible reversal to disclose sensitive and privileged information regarding their broad enforcement plans." Id. at 38-39. The government's purported "fears" are fanciful.[35/] The number of instances where a person would suffer a direct injury from an enforcement decision and thereby have standing to complain are few, and in those few cases, it certainly is not too much to require a good faith explanation from the agency of the rationale for its action or inaction. The purportedly "burdensome" court proceedings the government imagines would, in all likelihood, be decided, like

35/ Cf. Medical Committee for Human Rights v. SEC, supra, 432 F.2d at 675 ("experience indicates that the grim forebodings which are frequently expressed in this court regarding the possibility that a particular decision will cause irreparable disruption of the administrative process only rarely, if ever, come to pass."); Goodman v. United States, 424 F.2d 914, 918 (D.C. Cir. 1970).

the one in this case, on motions for summary judgment.[36/] The government's forebodings, when weighed against the express language of the statute and its legislative history, do not constitute "clear and convincing evidence" of congressional intent to preclude judicial review.

II. The Food and Drug Administration's Refusal to Enforce the FDCA to Ensure that Lethal Injection Drugs Produce A Quick and Painless Death Is An Abnegation of Its Statutory Duty and Is Arbitrary and Capricious.

An agency's enforcement decision which is in fact an abnegation of statutory responsibility cannot be defended as an exercise of good faith administrative discretion. Alternatively, agency action which is arbitrary and capricious is

36/ Indeed, prior cases in which the FDA has been ordered to comply with its statutory mandate and enforce the FDCA have not resulted in the dire consequences predicted by the government. See Hoffman-LaRoche, Inc. v. Weinberger, 425 F. Supp. 890 (D.D.C. 1975); American Public Health Association v. Veneman, 349 F. Supp. 1311 (D.D.C. 1972).

unlawful. 5 U.S.C. §706(2)(A). The FDA's wholesale refusal to enforce the FDCA on behalf of state prisoners facing execution by unapproved drugs is illegal under both these standards.

A. FDA's Refusal to Enforce the Act With Regard To Lethal Injection Is An Abnegation of Its Statutory Duty.

This Court has repeatedly and consistently condemned categorical refusals by an administrative agency to exercise its jurisdiction. Such wholesale refusals to act involve not merely an abuse of discretion, but action wholly beyond the agency's delegated power. In Office Employes International Union v. Labor Board, 353 U.S. 313 (1957), the question was whether the National Labor Relations Board could refuse to exercise jurisdiction over labor unions as a class when the unions were acting as employers themselves (of clerical workers, maintenance personnel, etc). The Court

first examined the National Labor Relations Act and found that unions clearly qualified as "employers" under the statutory definition and were potentially subject to the jurisdiction of the Board in this capacity. The question then became whether the Board could "by the application of general standards of classification, refuse to assert any jurisdiction over labor unions as a class" thereby "engraft[ing] a blanket exemption upon the Act." 353 U.S. at 314-15.

The Court ruled that the Board could not "renounc[e] jurisdiction over an entire category of employers," id. at 318, and that it was not "within the Board's discretion to remove unions as employers from the coverage of the Act after Congress had specifically included them therein," id. at 319. This was not the exercise of discretion but rather the abandonment of statutory responsibility: "the Board's declination of

jurisdiction was contrary to the intent of Congress, was arbitrary, and was beyond its power." Id. at 320. Allowing the Board to remove categories of employers from the Statute's broad coverage after Congress had included them would give the Board "the congressional power of repeal." Id. Accord: Leedom v. Kyne, 358 U.S. 184, 190 (1958) ("This Court cannot lightly infer that Congress does not intend judicial protection of rights it confers against agency action taken in excess of delegated powers."); Hotel Employees v. Leedom, 358 U.S. 99 (1958); Harmon v. Bruckner, 355 U.S. 579, 581-82 (1958); Stark v. Wickard, 321 U.S. 288, 310-11 (1944); Int'l. Union, United Auto. Aero. & Agric. Implement Workers v. NLRB, 427 F.2d 1330 (6th Cir. 1970); Safir v. Gibson, 417 F.2d 972, 978 (2d Cir. 1969) (ordered Federal Maritime Administration to review plaintiffs' complaint and to make a "considered decision").

In Adams v. Richardson, 480 F.2d 1159 (D.C. Cir. 1973) (en banc) (per curiam), the court held that the Secretary of HEW could not in effect refuse to enforce Title VI of the Civil Rights Act of 1964 to end segregation in schools receiving federal funds, and therefore ordered the Secretary to take enforcement measures. Similarly, in White v. Matthews, 559 F.2d 852 (2d Cir. 1977), cert. denied, 435 U.S. 908 (1978), the court ordered the Secretary of HEW to exercise his remedial powers under the Social Security Act.

Like the Board's attempted blanket exclusion of union employers as a class in Office Employes International Union, supra, and the Secretary's failure to exercise his enforcement and remedial powers in Adams v. Richardson and White v. Matthews, supra, the FDA's attempted categorical disregard of state misbranding of drugs, including their unauthorized use for lethal injection, is

contrary to the intent of Congress, arbitrary and beyond the agency's power: "FDA refused to take any action with regard to an entire category of allegedly prohibited activity." Pet. App. 35a n.45 (emphasis in original). The case law makes clear that such an abandonment by an agency of a statutorily mandated area of regulation is not the same as the exercise of good-faith investigative or enforcement discretion. Accordingly, FDA's attempt to carve from the FDCA an exemption for lethal injection here is unlawful and was properly set aside.

B. FDA's Refusal to Enforce the Act With Regard to Lethal Injection Is Arbitrary and Capricious.

In view of the complete administrative record and FDA's stated reasons for its inaction, FDA's decision not to enforce the FDCA with regard to the unapproved use of drugs for lethal injection is plainly arbitrary, capricious and without authority

of law. This is perhaps best demonstrated by the fact that FDA has abandoned its primary reason for non-enforcement following this reason's total rejection by both the court of appeals and the dissent below.[37/]

37/ The primary reason given by the FDA for rejecting respondents' administrative petition was that "the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction." Pet. App. 82a. Claiming that it lacked jurisdiction over the practice of medicine because physicians are licensed by the states, FDA analogically contended that it lacked jurisdiction over drugs used by prisons, which are also licensed by the states. Pet App. 84a. Both the court of appeals and the dissent resoundingly rejected this claim. Pet. App. 9a-12a, 54a. Judge Wright properly noted that the practice of medicine is exempt from FDA jurisdiction not because it is state-licensed, but because "Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses." Pet. App. 11a (footnote omitted). Judge Scalia agreed, observing that the majority opinion "properly demolishes the agency's reliance upon state action." Pet. App. 54a. The FDA's contention that it has no jurisdiction over state-licensed activity was particularly astounding, as Judge Wright noted, in light of the agency's regulation, over strenuous state objections, of drugs used in state prison clinical investigations, and of drugs used by state-licensed veterinarians to put animals to their death. Pet. App. 12a. See 21 C.F.R. § 50.44 (1983); Protection of Human Subjects; Prisoners Used as Subjects in

(Footnote Continued)

FDA now relies solely on the secondary "reasons" it originally offered to support its inaction, and on new rationalizations offered for the first time in this Court by counsel for the government. FDA's secondary reasons are merely variations of its unfounded, and now jettisoned, primary reason, and on that basis alone should be rejected. Even when viewed separately, untainted by the groundless nature of FDA's major argument, these secondary reasons are plainly irrational and arbitrary given the evidence in the record.

The FDA's unfounded claim that it has no jurisdiction over state-mandated activity is now couched in slightly different terms: the Act does not apply to state-mandated punishment, Br. for Pet. 42-46; FDA should be allowed to refuse enforcement if

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Research, 45 Fed. Reg. 36,388 (May 30, 1980) (rejecting states' claims that FDA has no jurisdiction over drugs used on state prisoners).

its jurisdiction is unclear, id. 47; regulating a state's use of drugs is not the FDA's central enforcement responsibility, id.; under principles of federalism, FDA should defer to a state's use of drugs for punishment, id. 48; a state's use of drugs on prisoners does not pose a danger to public health, id. All these "reasons" merely restate FDA's discredited claim that it has no jurisdiction over state-mandated activity, and for that reason alone they are arbitrary and capricious.

1. The FDCA Applies To State-Mandated Activity, Including Lethal Injection

a. The Supremacy of Federal Legislation

The government argues that FDA's decision not to enforce the FDCA with regard to lethal injection was rational because "there is no indication that any member of Congress even considered the possibility that enactment of the FDCA might affect"

state capital punishment. Br. for Pet. 44. This claim is identical to FDA's rejected argument below that it has no jurisdiction over lethal injection because it is state-mandated: the government revealingly prefaces its newly-worded claim by repeating the FDA Commissioner's assertion that "'the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction.'" Br. for Pet. 43. Once again, the government cites no authority for this myopic view of the broad protections provided by the FDCA and FDA's duties. The reason the government cites no authority to support its overly restrictive reading of the FDCA is clear: the express language of the statute, as well as the relevant precedents, are directly contrary to its crabbed interpretation.

The Secretary's claim that he does not have jurisdiction over drugs used in lethal injections is entitled to only the most

limited deference from this Court for numerous reasons. This position is inconsistent with longstanding FDA and court interpretations of the Act.[38/] See FEC v. Democratic Senatorial Campaign Committee, 454 U.S. 27, 37 (1981); Zenith Radio Corp. v. United States, 437 U.S. 443, 450 (1978). It is not based on any scientific or technical analysis peculiar to the agency's area of expertise. And it directly contradicts the express language of the statute as well as the congressional intent embodied in the Act as interpreted by numerous decisions of this Court.[39/]

38/ See Part I.B.2, 3, supra, for a discussion of prior FDA and court interpretations.

39/ Cf. Federal Power Commission v. Conway, 426 U.S. 271, 279 (1976) (FPC erroneously concluded that it lacked jurisdiction); Barlow v. Collins, 397 U.S. 159, 166 (1970) ("The role of the courts should, in particular, be viewed hospitably where ... the question sought to be reviewed does not significantly engage the agency's expertise"); Office of Consumers' Counsel v. Federal Engery Regulatory Comm'n 655 F.2d 1132, 1141-1142 (D.C. Cir. 1980) ("the question of FERC's jurisdiction is a legal (Footnote Continued)

Congress did not provide an express or implied exemption from the FDCA for state-mandated activity in general or for state lethal injection in particular. In the first place, the Supremacy Clause of the Constitution prempts any state law[40/] that conflicts with federal law. See, e.g., Arkansas v. Kansas and Texas Coal Co., 183 U.S. 185, 189 (1901) ("[i]t is true that when the police power and the commercial power come into collision, that which is not

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issue not implicating any expertise or specialized judgment which FERC possesses in other areas . . . This Court has the preeminent responsibility to independently scrutinize and decide all jurisdictional issues"); Elizabethtown Gas Co. v. Federal Energy Regulatory Comm'n, 575 F.2d 885, 887-889 (D.C. Cir. 1978) (agency erroneously concluded that it was powerless, as a matter of law, to order compensation to natural gas customers).

40/ The government concedes that "[s]tate law cannot interfere with lawful FDA action," Br. for Pet. 49 n.38, but argues that "the Supremacy Clause does not preclude the FDA from deferring to the states' considered judgment that lethal injection is the least painful method of capital punishment," id. There is absolutely no evidence that FDA refused enforcement for this reason, and no evidence, see J.A. 48-51, 69-71,78-80, that states have made such a "considered judgment."

supreme must give way to that which is supreme"). Where Congress has chosen to exercise its power over interstate commerce in a particular case, as it has with the FDCA, then any state legislation which conflicts, even a state's exercise of its own police power, must give way. United States v. Sullivan, 332 U.S. 689, 693 (1948); McDermott v. Wisconsin, 228 U.S. 115, 131-132 (1913).

More specifically, the Court has concluded that the FDCA should be interpreted broadly, even if doing so "would result in far-reaching inroads upon customary control by local authorities of traditionally local activities." United States v. Sullivan, supra, 332 U.S. at 693. This Court has emphatically rejected attempts to limit the scope of the Act by unfounded exemptions. See, e.g., United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798 (1969) ("Congress fully intended that the

Act's coverage be as broad as its literal language indicates -- and equally clearly, broader than any strict medical definition might otherwise allow").

Mostly recently, in United States v. Rutherford, 442 U.S. 544, 551-52 (1979), the Court held that implied exceptions should not be read into the Act except to prevent extreme and manifest anomalies:

> When construing a statute so explicit in scope, a court must act within certain well defined constraints. If a legislative purpose is expressed in 'plain and unambiguous language, . . . [the] duty of the courts is to give it effect according to its terms.' . . . Exceptions to clearly delineated statutes will be implied only where essential to prevent 'absurd results' or consequences obviously at variance with the policy of the enactment as a whole.

The Court in Rutherford held that no implicit exemption for a drug like Laetrile,

which was shipped in interstate commerce and used by the terminally ill, is necessary to attain congressional objectives or to avert an unreasonable reading of the terms "safe" and "effective" with respect to new drugs, despite the fact that "[s]eventeen States have legalized the prescription and use of Laetrile for cancer treatment within their borders." 442 U.S. at 554 n.10.

Likewise, there is nothing express or implied in the Act to suggest that the exemption of drugs used to kill human beings is necessary to fulfill the FDCA's purposes without absurdity. To the contrary, the FDA has vigorously applied the Act's requirements to drugs used to kill animals. See United States v. Beuthanasia-D Regular, [1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb. 1979). See FDA Policy Guide No. 7125.17, October 1, 1980 (regulating products intended for animal euthanasia).

Simply put, nothing in the legislative history of the Act, the case law interpreting it, or FDA's prior interpretations suggests that Congress intended that drugs used by the states to kill humans should be exempt from the Act. "It is not for us to speculate, much less act, on whether Congress would have altered its stance had the specific events of this case been anticipated." Tennessee Valley Authority v. Hill, 437 U.S. 153, 185 (1978). If dogs and horses are "consumers" who enjoy the protections afforded by Congress in the FDCA, then certainly prisoners who are administered drugs to produce death are also protected.

b. "Held for Sale"

The government's unsupported and unsupportable claim that the Act does not apply to state-mandated capital punishment is the sole basis for its argument that

there has been no prohibited misbranding of the lethal injection drugs while "held for sale" after their shipment in interstate commerce, and therefore no violation of 21 U.S.C. § 331(k).[41/] The government's "reasoning" flies in the face of the congressional intent underlying section 331(k) as expressly stated by Congress and of the consistently broad interpretations of the language of this section by this and other courts.

Congress enacted section 331(k) with the specific and explicitly stated intent to "extend the protection of consumers contemplated by the law to the full extent constitutionally permissible." H.R. Rep. No.

41/ A state prison's use of drugs as a means of lethal injection results in these drugs being misbranded under 21 U.S.C. 352(f) because the labels of these drugs do not contain either adequate directions for this unapproved use or adequate warning that this use may be dangerous or unsafe, to wit, directions or warnings which could prevent a slow, torturous death. See note 21, supra, and accompanying text.

2139, 75th Cong., 2d Sess. 3 (1938). This Court has expressly acknowledged that Congress intended section 331(k) to be construed broadly to fill the gap that would otherwise arise after a drug which has been transported in interstate commerce is misbranded by a person who neither shipped nor received the drug in interstate commerce:

> The words of paragraph (k) 'while such article is held for sale after shipment in interstate commerce' apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer.

United States v. Sullivan, supra, 332 U.S. 689, 696-697 (1948). See also Kordel v. United States, 335 U.S. 345, 351 (1948). In short, as a result of section 331(k), the Act unquestionably applies to the entire

distribution chain culminating with the ultimate user of the drugs.[42/]

The government in fact concedes as much: "We readily agree that Congress'

42/ See United States v. 10 Cartons, Labelled in Part "Hoxsey", 152 F. Supp. 360, 365 (W.D. Pa. 1957) ("[i]t is not the holding for sale in a technical legal sense which gives rise to the federal jurisdiction . . . but the fact that the channels of commerce have been used."); United States v. Sene X Eleemosynary Corp., 479 F. Supp. 970, 981 (S.D. Fla. 1979) ("[t]he 'held for sale' standard of section [331] has long been afforded a liberal reading"); United States v. Articles of Device [Acuflex; Pro-Med], 426 F. Supp. 366, 368 n.3 (W.D. Pa. 1977) ("[a]n article is 'held for sale' if it is used for any purpose other than personal consumption"); United States v. Device Labeled "Cameron, Spitler, Etc.", 261 F. Supp. 243, 246 (D. Neb. 1966). The government does not adopt Judge Scalia's hyper-technical, restrictive reading of section 331(k), which completely ignores the clear underlying congressional intent and this Court's consistent interpretation and application of this section. See, e.g., Kordel v. United States, 335 U.S. 345, 351 (1948). Indeed, the government admits that "[i]f a manufacturer or anyone else in the chain of distribution directly or indirectly were to suggest that a drug may properly be used for an unapproved use, the Act would be violated." Br. for Pet. 45 n.34. That is precisely the case presented here: the state prison officials, who are clearly in the chain of distribution, expressly suggest that they may properly use drugs for the unapproved use of lethal injection. As the government perhaps unwittingly concedes, such use is a violation of the Act.

purpose in enacting Section 331(k) was to extend the greatest possible protection to persons to whom drugs may be administered . . . ." Br. for Pet. 46. The government cites no authority for limiting the broad scope of § 331(k) to what it calls "conventional purposes." Id. And it does not even contest the court of appeals' holding that "Section 331(b) of the FDCA, which prohibits any misbranding in 'interstate commerce,' should be sufficiently broad to cover the actions of the state prisons in this case, given the modern constitutional understanding of the breadth of congressional power under the Commerce Clause." Pet. App. 14a. Thus, despite the government's half-hearted claims to the contrary, a state prison's use of drugs for lethal injection is prohibited by the express, unambiguous language of the Act because the channels of interstate commerce have been employed, 21 U.S.C. §§ 331(b), (k), and the drugs' use

for this purpose results in their being misbranded, 21 U.S.C. § 352(f).

2. The Uncontroverted Evidence Is That Lethal Injection Poses A Substantial Risk Of Inflicting A Slow, Torturous Death On Hundreds of Persons

The FDA Commissioner stated in his letter that lethal injection does not pose "a serious danger to the public health" because it is in accordance with "duly authorized statutory enactments in furtherance of proper state functions." Pet. App. 85a. This claim is nothing more than a variation of the discredited argument that state-licensed activity is exempt from FDA jurisdiction.

The "no-serious-danger" assertion has no other basis in the record. It was bottomed on the FDA's express refusal to consider the uncontroverted affidavits of expert anesthesiologists who stated unequivocally that the drugs and procedure

used in lethal injection present a substantial threat of torturous pain to persons being executed.[43/] In light of these affidavits, there is no foundation in fact for the FDA's unsubstantiated claim that the very real threat of a slow, agonizing death to hundreds of human beings[44/] is not a threat to public health. The irrational nature of this "reason" is particularly apparent in view of FDA's exercise of its regulatory

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43/ The FDA expressly ignored these affidavits as "not pertinent." Pet App. 86a.

44/ One of respondents' medical experts averred:

> "The determination of the proper dosage of drugs for a lethal injection would also be a difficult task . . . . If thiopental and tubocurarine were given in sequence, one might not be effective before the other. For example, if not enough thiopental were given and it were followed by curare, the prisoner could be awake and he would die in physical and mental agony."

J.A. 79-80.

jurisdiction to insure that drugs used to kill animals have been proven safe and effective before they are utilized. FDA Policy Guide No. 7125.17, October 1, 1980; United States v. Beuthanasia-D Regular, [1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb. 1979). If drugs used by state-licensed veterinarians to kill animals pose a serious threat to the "public health," then certainly drugs used to kill human beings pose at least as great a threat. Likewise, the FDA's suggestion that the threat of a slow, agonizing death to hundreds of human beings is not a threat to the "public health" because the persons are state prisoners is irrational in light of FDA's aggressive exercise of jurisdiction over state prisoners taking part in clinical investigations. 21 C.F.R. §§ 50.1 et seq.

Because this case was decided below on a motion for summary judgment, respondents' uncontroverted factual allegations that

lethal injection does not cause a "quick and painless" death and that it "poses a substantial threat of torturous and unnecessary pain to persons being executed" must be assumed to be true. J.A. 48-51, 69-71, 78-80. See Wolston v. Reader's Digest Association, Inc., 443 U.S. 157, 162 n.5 (1979); Bishop v. Wood, 426 U.S. 341, 347 n.11 (1976); United States v. Diebold, Inc., 369 U.S. 654, 655 (1962). Thus, the government's totally unsubstantiated claim, made for the first time by Judge Scalia, and not by the FDA, that lethal injection actually will result in less pain than other forms of execution is unavailable to the agency. There is nothing in the record to support this assertion. In point of fact, a major difference between lethal injection and the other forms of execution now mandated by the various states (asphyxiation

by lethal gas, electrocution,[45] hanging, shooting) is that the other forms (in theory) are designed to result in almost instantaneous death.[46] Lethal injection,

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45/ Proponents of electrocution contend that, unlike lethal injection, its effect on the victim is the instantaneous destruction of the nervous system, thereby precluding pain or any other sensation whatsoever. Gardner, Executions and Indignities -- An Eighth Amendment Assessment of Methods of Inflicting Capital Punishment, 39 OHIO ST. L. J. 96, 125 (1978).

46/ This case involves the enforcement obligations of the FDA as to "the unapproved use of approved drugs in state capital punishment systems." Pet. App. 3a. Lethal injection plainly involves prescription "drugs," as defined by the FDCA, which are being put to an "unapproved use." Lethal injection substances are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), and they are recognized in the official U.S. Pharmocopoeia, id., § 321(g)(1)(A). The FDA has indisputedly broad regulatory power over such "drugs," including the labeling of them. The Government's assertion that the decision below will have necessary implications for other traditional means of execution, Br. for Pet. 44, is fanciful, because the technical, statutory prerequisites for FDA jurisdiction are not present as to these methods of execution. The apparatus for electrocution, hanging, and shooting cannot reasonably be classified as a "device" under 21 U.S.C. § 321(h), for it is not listed in the National Formulary or the United States Pharmacopoeia, nor approved for some "diagnosis, cure, mitigation, treatment, or pre-
(Footnote Continued)

even if done "properly," results in death

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vention of disease," 21 U.S.C. § 321(h)(1), (2). Nor is it promoted for medical, therapeutic, or health purposes:

> "Anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man. Consequently any article which, used in the manner anticipated by the manufacturer thereof, comes into contact with any of the senses may be said to be an article 'intended to affect the functions of the body of man' . . . .
>
> Surely the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be."

Federal Trade Commission v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 576 (S.D.N.Y. 1952) (footnote omitted), aff'd, 203 F.2d 955 (2d Cir. 1953) (construing language in Federal Trade Commission Act identical to FDCA). Similarly, the industrial chemicals typically used in asphyxiation are not "drugs" under the FDCA because, inter alia, they have not been approved by the FDA for medical, therapeutic, or health purposes, nor are they promoted for such purposes. Cf. United States v. Article of Drug--OVA II, 414 F. Supp. 660, 665-666 (D.N.J. 1975), aff'd, 535 F.2d 1248 (3d Cir. 1976). For a substance to be classified as a "drug" on the ground that it "affects the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C), the vendor's intent in promoting the product for some medical, therapeutic, or health purpose is the key element, Action on Smoking and Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980) (Footnote Continued)

only after several minutes have elapsed.[47] The likelihood of miscalculation, bungling, and the unintentional infliction of pain is great with lethal injection.[48] See affidavits of Dr. Hodes, J.A. 69-71; Dr. Vandam, id. at 78-80; Dr. Casscells, id. at 48-51.

3. Prior FDA Enforcement Demonstrates the Irrationality of FDA's Non-Enforcement Here.

The Commissioner also stated that he would decline to exercise his jurisdiction because the case law was "far from uniform." Pet. App. 85a. The court of appeals properly rejected this claim as

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(upholding FDA ruling that "cigarettes will not be deemed a drug [under § 321(g)(1)(C)] unless health claims are made by the vendors," id. at 237 (footnote omitted)).

47/ Finks, Lethal Injection: An Uneasy Alliance of Law and Medicine, 4 J. LEGAL MED. 383, 397 (1983).

48/ See generally Christianson, Corrections Law Developments: Execution by Lethal Injection, 15 CRIM. L. BULL. 69 (Jan.-Feb. 1979); Finks, op. cit., supra, at 396-398.

nothing more than a variation of FDA's now abandoned claim that it had no jurisdiction. Pet. App. 32a-33a. In any event, this claim is frivolous in light of FDA's continued adherence to its 1972 policy statement with regard to preventing the unapproved use of approved drugs and its admission that it "will frequently act to prevent the sale of approved drugs for unapproved purposes by manufacturers, wholesalers, or distributors."[49/] See Part II.C.2, supra.

Likewise, FDA's purported deference to state-mandated activity is merely a thinly veiled rehash of its claim not to have jurisdiction over such activity. Moreover, only a few years ago, FDA rejected the argument it now embraces when it flatly rejected attempts by states to prevent its

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49/ Memorandum in Support of Defendant's Motion to Dismiss or, in the Alternative, for Summary Judgment, at 5 n.12.

application of the FDCA to state prisoners used in clinical investigations. 45 Fed. Reg. 36,388 (1980). See Part I.C., supra.

4. The FDA May Not Rely Upon Subsequent Rationalizations Of Counsel To Support Its Non-Enforcement Decision.

In recognition of the patent irrationality of the reasons given by the FDA to support its non-enforcement decision, the government claims for the first time in this Court that FDA "acted reasonably in conserving its limited enforement resources." Br. for Pet. 47. But as noted by the court of appeals, the "Commissioner has not asserted, at any point, that budgetary constraints would prevent FDA from investigating and taking appropriate action." Pet. App. 33a n.42. Courts properly review agency decisions only on the basis of the agency's stated reasons, and not on subsequent rationalizations of counsel. Burlington Truck Lines, Inc. v. United States, 371 U.S.

156, 168-169 (1962). Moreover, courts have rejected such arguments where Congress or the agency has promised that action will be taken, as both have done here. See e.g., Hoffman-LaRoche, Inc. v. Weinberger, 425 F. Supp. 890 (D.D.C. 1975); American Public Health Association v. Veneman, 349 F. Supp. 1311 (D.D.C. 1972).

The FDA Commissioner never suggested that his decision was motivated by a desire to conserve agency resources. The government's discovery now, for the first time, that the Commissioner's invocation of his purported "enforcement discretion" included such a motive is remarkable. Br. for Pet. 47-48, n.37. It is particularly remarkable inasmuch as the Commissioner expressly stated his "reasons" for refusing to exercise his jurisdiction, and limited resources was not one of them. Pet. App. 81a-86a. In any event, given the record in this case, FDA's prior enforcement record, and the

clear intent of Congress to protect all persons subjected to the use of drugs, any such category-wide claim by the Commissioner, had it been made, would be indefensibly arbitrary.

III. The Court Should Affirm The Decision of The Court Of Appeals Ordering The FDA To Comply With Its Statutory Duty And Enforce The FDCA To Ensure That Lethal Injection Drugs Produce A Quick And Painless Death

The FDA's categorical refusal to enforce the FDCA to ensure that lethal injection drugs produce a quick and painless death is "an abnegation of statutory responsibility by the very agency that Congress has charged with the task of ensuring that our people do not suffer harm from misbranded drugs." Pet. App. 38a. The only evidence before the FDA and in this record is respondents' scientific evidence that the lethal injection drugs planned to be used by the states are not "safe and effective." The FDA made no findings whatsoever as to

safety and effectiveness, but instead took the view that such information was not "pertinent" to its conclusion that it had no jurisdiction over lethal injection drugs:

> [Y]our petition contains many arguments that challenge the safety of the use of these drugs as execution agents. Because we have determined that the Federal Food, Drug, and Cosmetic Act does not provide us with authority to declare unlawful the use by State governments of drugs for lethal injection, the information is not pertinent to our conclusion.

Pet. App. 86a.

The Court should affirm the court of appeals' decision ordering the agency to comply with its congressional mandate by enforcing the FDCA. As a matter of course, the FDA uses its investigative and enforcement powers to assure that drugs employed by veterinarians for euthanasia purposes produce "the humane death of animals." United States v. Beuthanasia-D Regular,

[1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,265, at 39,129. Before it permits a dog to be killed, the FDA requires findings as to the safety and effectiveness of the drugs to be used. The FDCA requires the FDA to do for humans at least what it does for dogs.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

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APPENDIX

APPENDIX

(I.) 21 U.S.C. § 321(g)(1) and § 321(h) provide in pertinent part:

For the purposes of this chapter--

. . . .(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include

devices or their components, parts, or accessories.

. . . .(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnoses of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(II.) 21 U.S.C. § 331(b) and § 331(k) provide in pertinent part:

The following acts and the causing thereof are prohibited:

. . . .(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

. . . .(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not

the first sale) after shipment in inter-state commerce and results in such article being adulterated or misbranded.

(III.) 21 U.S.C. § 333(a) provides in pertinent part:

Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(IV.) 21 U.S.C. § 334(a)(1) provides in pertinent part:

Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any

time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found . . . .

(V.) 21 U.S.C. § 336 provides in pertinent part:

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(VI.) 21 U.S.C. § 352(f) provides in pertinent part:

A drug or device shall be deemed to be misbranded--

. . . . Unless its labeling bears (1) adequate directions for use; and (2)

such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(VII.) 21 U.S.C. § 355(a) and § 355(d) provide in pertinent part:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant

to subsection (b) of this section is effective with respect to such drug.

. . . .(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used

for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him in respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order

refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(VIII.) 5 U.S.C. § 706 provides in pertinent part:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an gency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(IX.) 21 C.F.R. § 201.5 provides in pertinent part:

"Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended. (Section 201.128 defines "intended use.") Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(a) Statements of all conditions, purposes, or uses for which such drug is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.

(c) Frequency of administration or application.

(d) Duration of administration or application.

(e) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(f) Route or method of administration or application.

(g) Preparation for use, i.e., shaking, dilution, adjustment of temperature, or other manipulation or process.

(X.) 21 C.F.R. §§ 10.85(d)-(f), and § 10.85(j) provide in pertinent part:

. . . .(d) A statement of policy or interpretation made in the following documents, unless subsequently repudiated by the agency or overruled by a court, will constitute an advisory opinion:

(1) Any portion of a FEDERAL REGISTER notice other than the text of a proposed or final regulation, e.g., a otice to manufacturers or a preamble to a proposed or final regulation,

(2) Trade Correspondence (T.C. Nos. 1-431 and 1A-8A) issued by FDA between 1938 and 1946.

(3) Compliance policy guides issued by FDA beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance standard for diagnostic X-ray systems, issued before July 1, 1975, and filed in a permanent public file for prior advisory opinions maintained by the Freedom of Information Staff (HFI-35).

(5) Guidelines issued by FDA under §10.90(b).

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) f this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion before amending or revoking the opinion. This action may be taken only with the approval of the Commissioner, who may not delegate this function. Appropriate amendment or revocation of the advisory opinion involved will be expedited.

. . . . (j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

REPLY

BRIEF

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No. 83-1878

In the Supreme Court of the United States

OCTOBER TERM, 1984

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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In the Supreme Court of the United States

OCTOBER TERM, 1984

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MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

LARRY LEON CHANEY, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

1. Respondents' submission depends almost entirely on a "strong presumption" favoring judicial review of "all final agency action" (Resp. Br. 19; see also *id.* at 19-40, 65-69)—perhaps in implicit recognition of the weakness of their argument that there is "law to apply" in this case.[1] However, respondents have not in any way refuted our contention (Pet. Br. 15-25) that no such presumption applies to administrative enforcement decisions and that, if anything, the presumption is precisely the reverse. See *Allen* v. *Wright*, No. 81-757 (July 3, 1984), slip op. 23 ("The Constitution, after all, assigns to the Executive Branch, and not to the Judicial Branch, the duty to 'take Care that the Laws be faithfully executed.' U.S. Const., Art. II, § 3.").

[1] Respondents also err in suggesting that FDA enforcement decisions are reviewable absent "'clear and convincing' evidence that Congress intended to prohibit judicial review" (Resp. Br. 65). See *Block* v. *Community Nutrition Institute*, No. 83-458 (June 4, 1984), slip op. 10-11.

Respondents' logic would require that even criminal prosecutorial decisions be reviewed by the courts, and respondents seem to suggest that such decisions are in fact reviewable to determine whether there has been an abuse of prosecutorial discretion (see Resp. Br. 23-24 & n.14). This is a sharp departure from this Court's precedents (see Pet. Br. 18).[2] Respondents also attempt to distinguish prosecutorial determinations from administrative enforcement decisions on the ground that "[c]riminal prosecutorial decisions are made to protect society as a whole," while administrative enforcement decisions directly affect classes of "individuals whom the statutes were enacted to protect" (Resp. Br. 26). This distinction is specious. Administrative enforcement is often designed primarily to protect the public. Certainly that is the chief purpose of FDA's enforcement actions under the FDCA. And criminal statutes, no less than statutes calling for administrative enforcement, often have the effect of protecting particular groups or individuals. Bank robbery statutes, for example, protect banks and bank employees; criminal statutes in the securities field protect investors. But it has never been held that such private parties may obtain judicial review under the APA of prosecutorial decisions they dislike.

Respondents cite a plethora of cases in an effort to show that enforcement decisions are freely reviewable, but respondents cite only one decision of this Court—*Dunlop* v. *Bachowski*, 421 U.S. 560 (1975)—in which the exercise of enforcement discretion was held to be reviewable

[2] This Court's suggestion (relied upon at Resp. Br. 25-26) in *Marshall* v. *Jerrico, Inc.*, 446 U.S. 238, 249-250 (1980), that a personal financial interest on the part of administrative prosecutors "may * * * in some contexts" raise due process concerns does not imply that prosecutorial determinations are presumptively reviewable. Moreover, respondents' reliance on *Jerrico* evidences the confusion that pervades their brief. Obviously once a law enforcement proceeding has been instituted, judicial review is available to ensure compliance with constitutional and statutory requirements. This case, of course, involves judicial review of a decision *not to bring* an enforcement proceeding.

under the APA. In our opening brief (at 23-25), we showed that *Bachowski* is easily distinguishable from the present case. Respondents state (Br. 30) that our characterization of *Bachowski* is "flatly wrong," but it is respondents who are in error. Respondents suggest (Br. 30-31) that the discussion in this Court's opinion concerned the question whether the Secretary of Labor's decision in that case was a matter "committed to agency discretion by law" and thus exempt from review under 5 U.S.C. 701(a)(2). Contrary to respondents' suggestion, this Court's discussion was limited to the separate question whether the Secretary's decision was exempt from review under 5 U.S.C. 701(a)(1) on the ground that Title IV of the Labor-Management Reporting and Disclosure Act of 1959 (LMRDA), 29 U.S.C. 481 *et seq.*, "preclude[s] review" (5 U.S.C. 701(a)(1)). The very portions of this Court's opinion that respondents quote (Br. 31-32) show that the discussion was restricted to 5 U.S.C. 701(a)(1). This Court did not discuss 5 U.S.C. 701(a)(2) but merely expressed agreement with the court of appeals' treatment of the issue (421 U.S. at 567 n.7). And in our opening brief (at 24-25), we demonstrated that none of the factors found by the court of appeals to support review in *Bachowski* is present in this case.[3]

Moreover, it is significant that the statutory scheme at issue in *Bachowski*, unlike the FDCA, did not grant unfettered enforcement discretion to the Secretary of Labor. Under Title IV of the LMRDA, the Secretary may not

[3] *Adams* v. *Richardson*, 480 F.2d 1159 (D.C. Cir. 1973), relied upon at Resp. Br. 28, 33-35, 73, involved allegations that the Department of Health, Education, and Welfare had adopted a "general policy" not to utilize specific statutory enforcement provisions contained in Title VI of the Civil Rights Act, with the result that HEW was "actively supplying segregated institutions with federal funds." 480 F.2d at 1162. In contrast, the FDA continues to utilize broadly all of its statutory enforcement provisions: no statutory language is nullified by its refusal to apply its enforcement authority in the particular area of lethal injections. Moreover, the FDA is obviously not engaged in affirmative support of activities contrary to congressional purposes.

bring suit to set aside a union election unless a union member exhausts his internal union remedies and files a complaint with the Secretary. See *Local 82* v. *Crowley*, No. 82-432 (June 12, 1984), slip op. 12. In that narrow circumstance, the Court concluded that Congress intended to permit *the complaining union member*—not any member of the general public—to bring suit pursuant to the APA to challenge the Secretary's exercise of discretion.[4] Here, by contrast, the FDA's enforcement discretion is not limited by statute, and respondents' submission, if accepted, would allow anyone to seek judicial review of the agency's decision not to bring enforcement proceedings under any portion of the Act.

Most of the remaining cases cited by respondents—and certainly all of the remaining decisions of this Court—are inapposite. Many do not involve enforcement activity at all,[5] much less an agency's *refusal* to take enforcement action in a particular case, which of course is what is at issue here. Still other cases cited by respondents (Br. 27, 28) involve an agency's refusal to promulgate regulations.[6] But since Congress often specifically intends for agencies to issue implementing regulations, such cases are easily distinguishable from cases involving an agency's refusal to take enforcement action in a particular case—a matter on which Congress rarely intends to restrict an agency's discretion. See also Pet. App. 45a-46a (Scalia, J., dissenting). Likewise, respondents' reliance on cases involving an agency's refusal to adjudicate disputes between private parties is misplaced.[7] While there is a strong tradition of prosecutorial and enforcement discretion, adjudicatory bodies do not customarily have the same discretion to decline to entertain cases falling within their jurisdiction.

2. Respondents acknowledge (Br. 40-41), as they must, that the FDA's decision in this case is unreviewable if there is "'no law to apply.'" *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 410 (1971), quoting S. Rep. 752, 79th Cong., 1st Sess. 26 (1945). Respondents have found no law to apply.

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[4] Indeed, the Court described the Secretary's role as "lawyer for the complaining union member" (421 U.S. at 572).

[5] *E.g.*, *Leedom* v. *Kyne*, 358 U.S. 184 (1958) (Resp. Br. 27, 72) (challenge to NLRB certification of a particular collective bargaining unit); *Harmon* v. *Brucker*, 355 U.S. 579 (1958) (Resp. Br. 72) (challenge to less than honorable military discharge); *Stark* v. *Wickard*, 321 U.S. 288 (1944) (Resp. Br. 72) (challenge to milk marketing order); *Carpet, Linoleum & Resilient Tile Layers* v. *Brown*, 656 F.2d 564 (10th Cir. 1981) (Resp. Br. 27) (challenge to agency refusal to comply with Davis-Bacon Act requirement that contractors pay local prevailing wages); *Pennsylvania* v. *National Association of Flood Insurers*, 520 F.2d 11 (3d Cir. 1975) (Resp. Br. 28) (challenge to failure to publicize flood insurance); *Davis* v. *Romney*, 490 F.2d 1360 (3d Cir. 1974) (Resp. Br. 28) (challenge to affirmative action of HUD in insuring mortgages on plaintiffs' homes); *Goodman* v. *United States*, 424 F.2d 914 (D.C. Cir. 1970) (Resp. Br. 68) (challenge to agency refusal to permit withdrawal of employee's resignation).

[6] *E.g.*, *NRDC* v. *EPA*, 683 F.2d 752 (3d Cir. 1982); *WWHT, Inc.* v. *FCC*, 656 F.2d 807 (D.C. Cir. 1981); *NRDC* v. *SEC*, 606 F.2d 1031 (D.C. Cir. 1979); *British Airways Board* v. *Port Authority*, 564 F.2d 1002 (2d Cir. 1977). *Rockbridge* v. *Lincoln*, 449 F.2d 567 (9th Cir. 1971).

[7] *E.g.*, *Hotel Employees* v. *Leedom*, 358 U.S. 99 (1958) (Resp. Br. 35-36, 72) (review of refusal to adjudicate labor disputes in hotel industry); *Office Employees Local No. 11* v. *NLRB*, 353 U.S. 313 (1957) (Resp. Br. 18g, 27, 70-72, 73) (review of refusal to resolve dispute between labor union and its employees); *Medical Committee for Human Rights* v. *SEC*, 432 F.2d 659 (D.C. Cir. 1970), vacated as moot, 404 U.S. 403 (1972) (Resp. Br. 25, 28, 68) (review of informal decision not to resolve proxy dispute between management and shareholder); *UAW* v. *NLRB*, 427 F.2d 1330 (6th Cir. 1970) (Resp. Br. 28, 72) (review of refusal to decide particular dispute between labor and management). See also *Safir* v. *Gibson*, 417 F.2d 972, 977 & n.6 (2d Cir. 1969), cert. denied, 400 U.S. 850 (1979) (Resp. Br. 72). Respondents also rely upon cases permitting review of agency delays in making quasi-judicial determinations. *Caswell* v. *Califano*, 583 F.2d 9 (1st Cir. 1978) (Resp. Br. 27, 37); *White* v. *Mathews*, 559 F.2d 852 (2d Cir. 1977), cert. denied, 435 U.S. 908 (1978) (Resp. Br. 27, 73). (These decisions, of course, are no longer good law. *Heckler* v. *Day*, No. 82-1371 (May 22, 1984).) Such review obviously does not implicate separation of powers concerns.

The bulk of respondents' discussion on this point (Br. 41-48, 58-65) confuses two entirely different concepts: law explaining what the FDCA prohibits and law setting forth standards for the exercise of the FDA's enforcement discretion. Only the latter has a bearing on whether the FDA's exercise of enforcement discretion is reviewable under the APA. Respondents instead rely on "criteria by which noncompliance with the [FDCA] can be determined" (Resp. Br. 41-48) and case law regarding what constitutes a violation of the FDCA (Resp. Br. 58-65). If respondents were correct, all prosecutorial decisions would be judicially reviewable. For example, the bank robbery statute (18 U.S.C. 2113) provides "criteria by which noncompliance with the [statute] can be determined," and there is abundant case law regarding what constitutes a violation of the statute. But that hardly means that a prosecutor's decision not to charge under the bank robbery statute is reviewable. What is critical is that neither the bank robbery statute nor the FDCA provides law to apply in the form of standards restricting the exercise of prosecutorial or administrative enforcement discretion.[8]

Respondents are thus relegated to relying on a few words taken out of context from a preamble to an unadopted regulation (Resp. Br. 45-58). This is a slender reed that cannot possibly bear the weight of respondents' argument.

In our opening brief, we showed (at 23-31) that the preamble did not purport to provide standards for the exercise of the FDA's enforcement discretion. Respondents have not attempted to answer this dispositive argument. We also argued (Pet. Br. 31-35) that the preamble did not bind the FDA in this case because the preamble is

[8] To the extent that respondents also rely upon statutory provisions that are not merely substantive requirements of the FDCA—*i.e.*, statutory language that violators "shall" receive specified penalties (Resp. Br. 43-44) and the provision of the FDCA regarding nonreporting of minor violations (21 U.S.C. 336) (Resp. Br. 45-48)—we have already demonstrated that such reliance is frivolous (see Gov't Br. 26-27 & n.16).

not a legislative rule and because the FDA's own rules do not regard the preamble as having binding effect in this context. Respondents contend (Br. 57-58 & n.29) that the preamble need not be a legislative rule in order to provide "law to apply." However, respondents have not cited any authority that supports this proposition.[9] Respondents also disagree with the FDA's interpretation of its rules regarding advisory opinions (Resp. Br. 53-57), but respondents' alternative interpretation—that advisory opinions always bind the FDA but do not bind adversely affected third parties—is not supported by the language of the rules or by any cited authority. In any event, the FDA is the best judge of its own regulations.[10]

Respondents have also made virtually no response (see Resp. Br. 66 n.33) to the legislative history of the FDCA, which demonstrates Congress's understanding that the FDA would have no judicially cognizable duty to initiate proceedings to enforce the Act. See Pet. Br. 39-42. Contrary to respondents' characterization, the excerpts we relied on do not refer solely to FDA's "limited 'discretion' under 21 U.S.C. § 336" (Resp. Br. 66 n.33). The excerpts speak for themselves and show that Congress clearly

[9] In *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944), on which respondents rely (Br. 58 n.29), the Court did not hold that an informal agency pronouncement furnishes law to apply under the APA (this was of course a pre-APA case) or that such a statement binds the agency in any other way. The Court merely took note of the Wage and Hour Administration's interpretive bulletins in deciding a question of statutory construction under the Fair Labor Standards Act.

[10] *United States* v. *Ewig Bros.*, 502 F.2d 715, 725 n.34 (7th Cir. 1974), an action brought by the government to enjoin distribution of fish contaminated by DDT, is inapposite. There, an FDA press release purporting to set tolerance limits for DDT in food was regarded as a legislative rule because the language of the press release suggested that it was intended to have such an effect and because the government had apparently prosecuted the case at trial and on appeal on the theory that the press release was binding. See *id.* at 724-725 & nn.31-34. No similar circumstances are present here.

intended for the FDA to have unreviewable enforcement discretion.

3. Finally, respondents have failed to show that the FDA abused its discretion in not investigating the means used by the states in carrying out capital punishment. First, the FDA lacks jurisdiction over the use of approved drugs by state authorities for capital punishment purposes. It is a sheer contradiction in terms for respondents to contend that the FDA has "abandoned" (Resp. Br. 75) and "jettisoned" (Resp. Br. 76) its original position in this regard, while at the same time arguing that the FDA's present position is "identical" to (Resp. Br. 78) and only "couched in slightly different terms" from (Resp. Br. 76) that original position.[11] Respondents' reliance on the Supremacy Clause (Resp. Br. 80-81) is also an irrelevant distraction, for while the Supremacy Clause provides for the preemptive effect of federal law (Resp. Br. 80-81), the Clause does not assist in construing the extent of jurisdiction provided by a particular federal statute.

In our opening brief (at 43-37), we argued that the FDA lacked jurisdiction because the drugs at issue here are not literally "held for sale" when administered to prisoners and because there is not a scintilla of evidence that Congress intended for the FDCA to regulate capital punishment. We noted (Pet. Br. 44) that respondents' contrary interpretation would lead to the absurd result of requiring the FDA to regulate such traditional means of capital punishment as the gas chamber, electric chair, and gallows. Respondents' argument that electric chairs and gallows do not fit within the statutory definition of "device," while the drugs used for lethal injections do fit within the statutory definition of "drug" (Resp. Br. 93-95 n.46), is based on a strained reading of the two statutory definitions. See 21 U.S.C. 321(g)(1), 321(h). Each definition contains three categories, any one of which

[11] Contrary to respondents' assertion (Resp. Br. 18c, 43 n.21), the government does not agree that drugs used for lethal injections are necessarily misbranded. See Pet. Br. 46.

serves to meet the broad statutory requirements: first, articles recognized in an official compendium (21 U.S.C. 321(g)(1)(A), 321(h)(1)), second, articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" (21 U.S.C. 321g(1)(B), 321(h)(2)), *and* third, articles "intended to affect the structure or any function of the body of man or other animals" (21 U.S.C. 321(g)(1)(C), 321(h)(3)).[12] It is absurd for respondents to suggest that means for carrying out capital punishment are not "intended to affect the structure or any function of the body of man." Such an argument, in addition to ignoring the words of the Act, would eviscerate the FDA's ability to regulate articles that do not fit within the first two categories, thus frustrating congressional intent in providing a third, separate category.

Moreover, apart from what Congress may have intended the FDCA to mean, the FDA's uncertainty about how the courts would greet any attempt to assert authority over state-mandated executions is a fully adequate basis for an agency with limited resources to decline proposed enforcement efforts. See Pet. Br. 47; Pet. App. 85a. Respondents rely repeatedly and extensively upon the FDA's actions regarding drugs used to kill animals (Resp. Br. 18, 61-63, 83, 91, 100-101) and drugs used on human prisoners for research (Resp. Br. 18h, 63-64, 96-97). In these situations, however, the FDA was on much sounder jurisdictional footing than it would have been with regard to the enforcement proceedings sought by respondents.

In *United States* v. *Beuthanasia-D Regular*, [1979 Transfer Binder] Food Drug Cosm. L. Rep. (CCH ¶ 38,265 (D. Neb. Aug. 1, 1979), the FDA did not assert authority over the *use* of drugs to kill animals. That case involved instead a situation in which a manufacturer was *marketing* a drug for purposes of animal euthanasia. Thus the case was of the type in which FDA normally

[12] The definition of a drug also contains a fourth category that extends the definition to components of articles specified in the other three categories (21 U.S.C. 321(g)(1)(D)).

assumes jurisdiction—the marketing and promotion by a manufacturer of a drug for a purpose that has not been subject to premarketing approval.[13]

Similarly, unlike its doubtful authority to regulate drugs used for administration of the death penalty, the FDA has clear statutory authority to regulate the use of drugs in a research involving prisoners. The FDA has authority over all research investigations, whether or not involving prisoners, because drugs used in investigations are manufactured and shipped for that purpose. To ship such research drugs without first having obtained FDA approval (21 U.S.C. 351(i)) is a violation of 21 U.S.C. 355(a) and 331(d) because the FDA has explicit statutory authority to regulate the distribution of drugs for research. The regulations referred to by respondents (Resp. Br. 63-64, 96-97) simply implement Section 355(i) and other similar FDA statutory authorizations. See 21 U.S.C. 357(d), (360)(g).

Finally, respondents (Resp. Br. 89-95) and amici Public Citizen and American Society of Law and Medicine, et al., argue that the FDA was legally obligated to intervene because lethal injection is a less desirable means of capital punishment than other methods. Whatever the merits of this argument—and there is surely much to be said on the other side[14]—it is an argument that should

[13] Even were this not the case, the agency would still have clearer statutory authority to intervene in a situation involving the unapproved use of animal as opposed to human drugs. 21 U.S.C. 360b(a)(1) specifically provides that without approval a new animal drug "with respect to any particular *use* or intended *use*" (emphasis added) is "unsafe" and therefore "adulterated" as a matter of law under 21 U.S.C. 351(a)(5). No comparable provision exists with respect to human drugs. Under 21 U.S.C. 331(k), "adulteration" serves as an alternative to "misbrand[ing]."

[14] For contrary expert opinion, see Kemperman, *Medical Involvement in Capital Punishment*, The Lancet, Feb. 5, 1983, at 301-302; *Death Row and the Medical Model*, Hastings Center Rep., Oct. 1979, at 5; Nichols, *Lethal Injection Rarely Used Execution Method*, Chi. Daily L. Bull., Mar. 19, 1984, at 3; Note, *Criminal Procedure—Capital Punishment—Texas Statutes Amended to Provide for Executions by Intravenous Injection of a Lethal Substance*, 9 St. Mary's L.J. 359, 364-365 (1977).

be addressed to bodies other than the FDA—to courts, which must review death sentences and may be called upon to determine whether execution by lethal injection satisfies Eighth Amendment standards, and to state legislatures, which in increasing numbers are concluding, after studying the available evidence, that lethal injection is the least painful method of execution. The FDA has no experience or particular expertise in making a comparative assessment of different methods of capital punishment, nor does it have a congressional mandate to venture into this field. The FDA thus properly declined to intervene.

For the foregoing reasons and those stated in our opening brief, it is respectfully submitted that the judgment of the court of appeals should be reversed.

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NOVEMBER 1984

Respondents argue (Br. 10-11) that since doctors are ethically barred from administering lethal injections the chances that something will go wrong are increased. But as the British Royal Commission on Capital Punishment observed more than 30 years ago (*1949-1953 Report of the Royal Commission on Capital Punishment* 259 (1953)), "it is not only within the profession that the necessary skill is to be found. There are many outside it who are fully competent either to give injections themselves or to train others to do it." See also Bolsen, *Strange Bedfellows: Death Penalty and Medicine*, 248 J.A.M.A. 518, 518-519 (1982); see Malone, *More Humane? First Execution by Injection*, 69 A.B.A. J. 143 (1983); N.J. Stat. Ann. § 2C: 49-2 (West 1984) (specifies use of "execution technicians").

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